

SURGICRAFT

FEB 15 2011

510(k) Summary

Contact: Donald W. Guthner
Orgenix, LLC
111 Hill Road
Douglassville, PA 19518
(646) 460-2984

Device Trade Name: *LOCKDOWN™ Acromioclavicular (AC) device.*

Manufacturer: Surgicraft (Trading Name of Mandaco 569 Limited)
16 The Oaks
Clews Road
Redditch, UK
B98 7ST

Classification: 21 CFR 888.3030, Single/multiple component metallic bone fixation appliances and accessories

Class: II

Product Code: HTN

Indications For Use:

The Surgicraft *LOCKDOWN™ Acromioclavicular (AC) device* is indicated to provide fixation during the healing process following a syndesmotic trauma, such as fixation of acromioclavicular separations due to coracoclavicular ligament disruptions.

Device Description:

The Surgicraft *LOCKDOWN™ Acromioclavicular (AC) device* is a combination of two FDA-cleared Surgicraft Products, the Surgicraft LOCKDOWN Mesh (K072370) and the Surgicraft LOCKDOWN Screw (K080447). The new product for this indication is designated as the *LOCKDOWN™ Acromioclavicular (AC) device* and will have a new indication to provide fixation during the healing process following a syndesmotic trauma, such as fixation of acromioclavicular separations due to coracoclavicular ligament disruptions.

It is not intended that the Surgicraft *LOCKDOWN™ Acromioclavicular (AC) device* be used as the sole means of reconstructing a chronic acromioclavicular joint dislocation.

The *Surgicraft LOCKDOWN Mesh* device is a woven mesh 11mm wide by 4 to 20 cm in length with loops at both ends. The Surgical Mesh is made from braided Polyethyleneterephthalate (Polyester) fibers (PET).

Manufactured by:

Surgicraft (Trading name of Mandaco 569) / 16 The Oaks / Clews Road / Redditch / Worcestershire / B98 7ST / UK
T: +44 1527 512600 / F: +44 1527 512612 / E: info@surgicraft.co.uk / www.surgicraft.co.uk

K011267

The *Surgicraft LOCKDOWN Screw* is manufactured from stainless steel and titanium alloy. The self-tapping 3.5 mm screws are available in lengths from 14- 40 mm in 1 mm increments. The washers have a hole with an inner diameter of 4.2 mm and an outer diameter ranging from 7 to 9 mm in 1 mm increments.

The Surgicraft *LOCKDOWN™ Acromioclavicular (AC) device* is provided sterile.

Predicate Device(s):

The Surgicraft *LOCKDOWN™ Acromioclavicular (AC) device* was shown to be substantially equivalent to the Arthrex TightRope® Acromioclavicular device (K052776) and has the same indications for use, function and/or materials.

- The Surgicraft *LOCKDOWN™ Acromioclavicular (AC) device* and the named predicate device both use braided Polyethyleneterephthalate (Polyester) fibers (PET), stainless steel and titanium materials to fixate acromioclavicular separations.
- Both devices contraindicate the use of the device as the sole means of reconstructing a chronic acromioclavicular joint dislocation.
- The indications for use statements for both devices are identical.

Performance Standards:

No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act applicable to this device. Side-by-side testing was performed with the named predicate device in appropriate cadaver models and indicated that the Surgicraft *LOCKDOWN™ Acromioclavicular (AC) device* is substantially equivalent to predicate device.

Non-Clinical Testing

Mechanical testing was performed on the Surgicraft *LOCKDOWN™ Acromioclavicular (AC) device* or its components prior to submission for approval. Testing performed included biocompatibility testing (per ISO 10993), screw pull-out testing, mesh burst strength and suture attachment strength. In addition, side-by-side testing was performed against the predicate device in an appropriate cadaveric model.

Clinical Testing

No clinical testing was performed nor was deemed necessary to demonstrate substantial equivalence.

Conclusions

Surgicraft considers the *LOCKDOWN™ Acromioclavicular (AC) device* to be equivalent to the predicate device listed above. This conclusion is based upon the devices similarities in function, materials and indications for use.





DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring, MD 20993-0002

Surgicraft, Ltd.
% Mr. Donald W. Guthner
Orgenix, LLC
111 Hill Road
Douglassville, Pennsylvania 19518

FEB 15 2011

Re: K091207

Trade/Device Name: Surgicraft LOCKDOWN™ Acromioclavicular (AC) device
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HTN
Dated: January 5, 2010
Received: January 6, 2010

Dear Mr. Guthner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

Page 2 – Mr. Donald W. Guthner

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

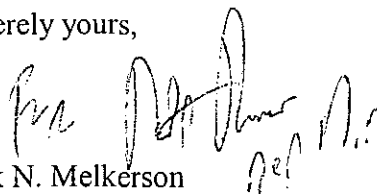
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucml15809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SURGICRAFT

Indications for Use

510(k) Number (if known): K091207

Device Name: **Surgicraft LOCKDOWN™ Acromioclavicular (AC) device**

The Surgicraft *LOCKDOWN™ Acromioclavicular (AC) device* is indicated to provide fixation during the healing process following a syndesmotic trauma, such as fixation of acromioclavicular separations due to coracoclavicular ligament disruptions.

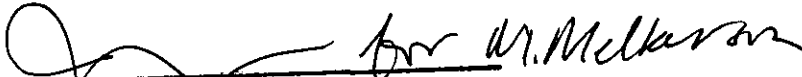
Prescription Use √
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091207

Amendment 1

K091207/A1



CRO Services Clinical Regulatory Reimbursement

January 14, 2010

Office of Device Evaluation, 510(k)
Center of Devices and Radiological Health
Document Mail Center (WO66-0906)
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA CDRH DMC
JAN 15 2010
Received

RE: K091207/S1 – 510(k) Application – Surgicraft LOCKDOWN™ AC
Attn: Document Control Clerk

Dear Sir/Madam,

Orgenix, LLC is performing the role of consultant on behalf of:

Surgicraft Limited.

In preparation of the S1 submission, incorrect versions of three documents were inadvertently included in the submission. The correct pages of the documents are being submitted as an “Add to File.” We are submitting the attached pages as an “add to file” to replace the pages which we are requesting to be removed.

Page Numbers to be Removed from submission K091207/S1 dated January 5, 2010	To be replaced by the attached pages numbering:	Comment
Att. 1 - 13	Att. 1 - 13	Addition of “Manufactured by”
Att. 1 – 27 to Att. 1 - 28	Att. 1 – 27 to Att. 1 - 28	Revised IFU
Att. 2- 1 to Att. 2 - 17	Att. 2- 1 to Att. 2 - 17	TR_333-0909-13824_Rev2

We consider our intent to market this device as confidential commercial information and request that it be considered as such by FDA.

We would appreciate FDA’s earliest attention to this Section 510(k) submission.

Sincerely,

Donald W. Guthner
Principal
Orgenix, LLC

On behalf of
Surgicraft Ltd.

K2

111 Hill Road * Douglassville, PA 19518
(646) 460-2984 * (888) ORGENIX * (484) 363-5879 (FAX)
www.orgenix.com



see A2

LockDown™ Acromioclavicular (AC) Device

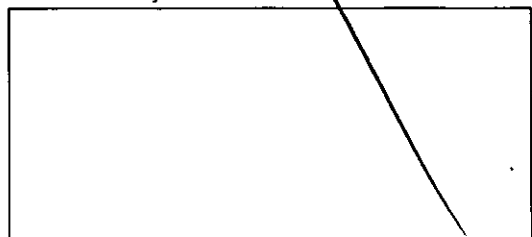
CODE	DESCRIPTION
LD050	LockDown™ 5cm Acromioclavicular (AC) Device*
LD060	LockDown™ 6cm Acromioclavicular (AC) Device*
LD070	LockDown™ 7cm Acromioclavicular (AC) Device
LD080	LockDown™ 8cm Acromioclavicular (AC) Device
LD090	LockDown™ 9cm Acromioclavicular (AC) Device
LD100	LockDown™ 10cm Acromioclavicular (AC) Device
LD110	LockDown™ 11cm Acromioclavicular (AC) Device
LD120	LockDown™ 12cm Acromioclavicular (AC) Device
LD130	LockDown™ 13cm Acromioclavicular (AC) Device
LD140	LockDown™ 14cm Acromioclavicular (AC) Device*
LD150	LockDown™ 15cm Acromioclavicular (AC) Device*
LD160	LockDown™ 16cm Acromioclavicular (AC) Device*
LD170	LockDown™ 17cm Acromioclavicular (AC) Device*
LD180	LockDown™ 18cm Acromioclavicular (AC) Device*
LD190	LockDown™ 19cm Acromioclavicular (AC) Device*
LD200	LockDown™ 20cm Acromioclavicular (AC) Device*
LDLG	LockDown™ Length Gauge
LDSS14	14mm Cortical Screw (3.5mm Dia) & 1mm Washer (SS)
LDSS16	16mm Cortical Screw (3.5mm Dia) & 1mm Washer (SS)
LDSS18	18mm Cortical Screw (3.5mm Dia) & 1mm Washer (SS)
LDSS20	20mm Cortical Screw (3.5mm Dia) & 1mm Washer (SS)
LDSS22	22mm Cortical Screw (3.5mm Dia) & 1mm Washer (SS)
LDSS24	24mm Cortical Screw (3.5mm Dia) & 1mm Washer (SS)
LDSS26	26mm Cortical Screw (3.5mm Dia) & 1mm Washer (SS)
LDSS28	28mm Cortical Screw (3.5mm Dia) & 1mm Washer (SS)
LDSS30	30mm Cortical Screw (3.5mm Dia) & 1mm Washer (SS)
LDSS32	32mm Cortical Screw (3.5mm Dia) & 1mm Washer (SS)
LDSS34	34mm Cortical Screw (3.5mm Dia) & 1mm Washer (SS)
LDSS36	36mm Cortical Screw (3.5mm Dia) & 1mm Washer (SS)
LDSS38	38mm Cortical Screw (3.5mm Dia) & 1mm Washer (SS)
LDSS40	40mm Cortical Screw (3.5mm Dia) & 1mm Washer (SS)

* Special sizes available on request only.

Surgicraft
 (Trading Name of Mandaco 569 Limited)
 16 The Oaks
 Clews Road
 Redditch
 Worcestershire
 B98 7ST
 ENGLAND

Tel: +44(0)1527 555888
 Fax: +44(0)1527 551166
 customerservice@surgicraft.co.uk
 www.surgicraft.co.uk

Distributed by:



Manufactured by:
 Surgicraft (Trading Name of Mandaco 569 Limited)
 16 The Oaks, Clews Road, Redditch, UK, B98 7ST
 www.surgicraft.co.uk info@surgicraft.co.uk



SURGICRAFT

LockDown™ Acromioclavicular (AC) Device

Instructions for Use

A. INDICATIONS

The Surgicraft LockDown™ Acromioclavicular (AC) Device is intended to provide fixation during the healing process following a syndesmotic trauma, such as acromioclavicular separation, due to coracoclavicular ligament disruption.

B. CONTRAINDICATIONS

1. Insufficient quantity or quality of bone.
2. Blood supply limitations and previous infections, which may tend to retard healing.
3. Foreign-body sensitivity. Where material sensitivity is suspected, appropriate tests should be made and sensitivity ruled out prior to implantation.
4. Any active infection.
5. Conditions which tend to limit the patient's ability or willingness to restrict activities or follow directions during the healing period.
6. The use of this device may not be suitable for patients with insufficient or immature bone. The physician should carefully assess bone quality before performing orthopaedic surgery on patients who are skeletally immature. The use of this medical device and the placement of hardware or implants must not bridge, disturb, or disrupt the growth plate.
7. Do not use for surgeries other than those indicated.

C. ADVERSE EFFECTS

1. Infections, both deep and superficial.
2. Allergies and other reactions to device materials.

D. WARNINGS

1. All metal implants used for this surgical procedure must have the same metallurgical composition.
2. Postoperatively, until healing is complete the fixation provided by this device should be protected. The postoperative regimen prescribed by the physician should be strictly followed to avoid adverse stress to the implant.
3. Detailed instructions on the use and limitations of the device should be given to the patient.
4. Any decision to remove the device should take into consideration the potential risk to the patient of a second surgical procedure. Implant removal should be followed by adequate postoperative management.
5. Preoperative and operating procedures, including knowledge of surgical techniques and proper selection and placement of the implant, are important considerations in the successful utilisation of this device.
6. An internal fixation device must never be reused.
7. Do not re-sterilise this device.
8. The appropriate Surgicraft instrumentation is required for proper insertion of the implant.
9. Once open, discard any unused device.
10. Do not expose the mesh to heat.

Manufactured by:

Surgicraft (Trading name of Mandaco 569) / 16 The Oaks / Clews Road / Redditch / Worcestershire / B98 7ST / UK
T: +44 1527 512600 / F: +44 1527 512612 / E: info@surgicraft.co.uk / www.surgicraft.co.uk

A4

SURGICRAFT

E. PACKAGING AND LABELING

1. Surgicraft implants should be accepted only if the factory packaging and labelling arrive intact.
2. Contact Customer Service if package has been opened or altered.

F. STERILISATION

This device is supplied sterile. Refer to the package label for the sterilisation method. Certain Surgicraft instruments that may be used during this procedure are provided non sterile and must be adequately cleaned and sterilised prior to use or re-use. Please refer to DFU-0023 and ANSI/AAMI ST46, "Good Hospital Practice: Steam Sterilisation and Sterility Assurance" for specific information.

G. MATERIAL SPECIFICATIONS

LockDown™ Acromioclavicular (AC) Device: Stainless Steel Screw and Washer to F138; and ISO5832-1 or Titanium Alloy Screw and Washer 6Al4V to F136; and ISO5832-3.

LockDown™ Mesh: Polyethyleneterephthalate, ie Polyester Fibres (PET)

H. STORAGE CONDITIONS

The LockDown™ Acromioclavicular (AC) Device must be stored in the original unopened packaging, away from moisture and should not be used after the expiration date.

I. INFORMATION

For more information, or a demonstration, contact your local Surgicraft representative.

J. DIRECTIONS FOR USE

Users of these devices are encouraged to contact their Surgicraft representatives if, in their professional judgment, they require a more comprehensive surgical technique.

K. CAUTION

The LockDown™ Acromioclavicular (AC) Device has not been evaluated for safety and compatibility in the MR environment. The LockDown™ Acromioclavicular (AC) Device has not been tested for heating or migration in the MR environment.

Federal Law (U.S.A.) restricts LockDown™ Acromioclavicular (AC) Device to sale by or on the order of a physician. Only physicians qualified in appropriate surgical technique should use this device.

Manufactured by:

Surgicraft (Trading name of Mandaco 569) / 16 The Oaks / Clews Road / Redditch / Worcestershire / B98 7ST / UK
T: +44 1527 512600 / F: +44 1527 512612 / E: info@surgicraft.co.uk / www.surgicraft.co.uk



TITLE: TEST REPORT FOR THE MECHANICAL ASSESSMENT OF THE SURGICRAFT LOCKDOWN™ ACROMIOCLAVICULAR (AC) FIXATION SYSTEM AND A PREDICATE COMPARISON

CONFIDENTIAL

SPONSOR: Surgicraft
16 The Oaks
Clews Road
Redditch, Worcestershire
B98 7ST

PROTOCOL NUMBER: TR_333-0909-13824_Rev2

PROTOCOL DATE: December 24, 2009

PROTOCOL PREPARATION:

(b) (4)

A large black rectangular redaction box covers the majority of the text under 'PROTOCOL PREPARATION'. The text '(b) (4)' is visible in the top-left corner of the redacted area.

Signed and Dated December 24, 2009

Records processed under FOIA Request # 2015-684; Released by CDRH on 10-08-2015

Records processed under FOIA Request # 2015-684; Released by CDRH on 10-08-2015

Records processed under FOIA Request # 2015-684; Released by CDRH on 10-08-2015

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Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring, MD 20993-0002

Surgicraft, Ltd.
% Mr. Donald W. Guthner
Orgenix, LLC
111 Hill Road
Douglassville, Pennsylvania 19518

FEB 15 2011

Re: K091207

Trade/Device Name: Surgicraft LOCKDOWN™ Acromioclavicular (AC) device
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HTN
Dated: January 5, 2010
Received: January 6, 2010

Dear Mr. Guthner:

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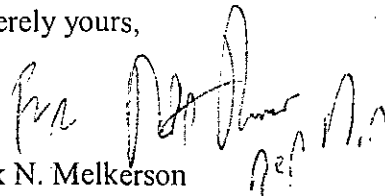
Page 2 – Mr. Donald W. Guthner

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Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SURGICRAFT

Indications for Use

510(k) Number (if known): K091207

Device Name: **Surgicraft LOCKDOWN™ Acromioclavicular (AC) device**

The Surgicraft *LOCKDOWN™ Acromioclavicular (AC) device* is indicated to provide fixation during the healing process following a syndesmotic trauma, such as fixation of acromioclavicular separations due to coracoclavicular ligament disruptions.

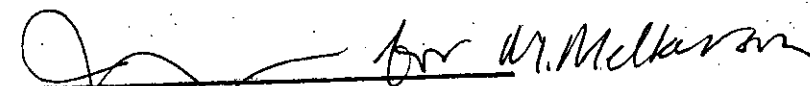
Prescription Use
 (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
 (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number

K091207

3



U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

October 16, 2009

SURGICRAFT LTD.
C/O ORGENIX, LLC
111 HILL ROAD
DOUGLASSVILLE, PENNSYLVANIA 19518
UNITED STATES
ATTN: DONALD W. GUTHNER

510k Number: K091207

Product: SURGICRAFT SURGILIG ACROMIOCLA

Extended Until: 01/06/2010

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information (AI) is not received by the "Extended Until" date shown above, your premarket notification will be considered withdrawn (21 CFR 807.87(l)). If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

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U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

October 06, 2009

SURGICRAFT LTD.
C/O ORGENIX, LLC
111 HILL ROAD
DOUGLASSVILLE, PENNSYLVANIA 19518
UNITED STATES
ATTN: DONALD W. GUTHNER

510k Number: K091207

Product: SURGICRAFT SURGILIG ACROMIOCLA

Extended Until: 12/15/2009

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

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If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

186



October 5, 2009

U.S. Food and Drug Administration
Center of Devices and Radiological Health
Document Mail Center (WO66-0906)
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA CDRH DMC

OCT 16 2009

Received

RE: K091207 – Surgicraft Acromioclavicular Device
Request for response deadline extension

Reviewer: Elizabeth Frank

Dear Sir/Madam,

I am writing on behalf of my client, Surgicraft Limited located in Redditch, UK. Orgenix is the US Agent for this company.

This letter is sent in response to the correspondence dated July 10, 2009 received from FDA regarding the deficiencies noted during the review of the above referenced 510(k) submission.

The Sponsor wishes to carefully consider and prepare their responses to the listed items in order to provide sufficient information to FDA to achieve a successful clearance of this product. However, in order to complete the testing required, to obtain the necessary predicate data and to schedule the participation of a surgeon in cadaveric testing, the amount of time to adequately reply will encroach upon the 180-day timeframe FDA normally permits a 510(k) to remain on hold. I have roughly calculated that date to be on or around January 9, 2010. The Sponsor would beg the forbearance of FDA to extend the response time for 30 additional days until February 9, 2010 in order to complete the on-going testing.

We appreciate your attention to this request.

Regards,

Donald W. Guthner
Principal

1020

111 Hill Road * Douglassville, PA 19518
(646) 460-2984 * (888) ORGENIX * (484) 363-5879 (FAX)
www.orgenix.com

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CRO Services Clinical
Regulatory
Reimbursement

October 5, 2009

U.S. Food and Drug Administration
Center of Devices and Radiological Health
Document Mail Center (WO66-0906)
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Received

OCT - 6 2009

RE: K091207 – Surgicraft Acromioclavicular Device
Request for response deadline extension

FDA CDRH DMC

Reviewer: Elizabeth Frank

Dear Sir/Madam,

I am writing on behalf of my client, Surgicraft Limited located in Redditch, UK. Orgenix is the US Agent for this company.

This letter is sent in response to the correspondence dated July 10, 2009 received from FDA regarding the deficiencies noted during the review of the above referenced 510(k) submission.

The purpose of this letter is to request an additional 45-day extension to the October 8, 2009 deadline.

The Sponsor wishes to carefully consider and prepare their responses to the listed items in order to provide sufficient information to FDA to achieve a successful clearance of this product.

Regards,

Donald W. Guthner
Principal

1037

111 Hill Road * Douglassville, PA 19518
(646) 460-2984 * (888) ORGENIX * (484) 363-5879 (FAX)
www.orgenix.com

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Surgicraft, Ltd.
% Mr. Donald W. Guthner
Orgenix, LLC
111 Hill Road
Douglassville, Pennsylvania 19518

JUL 10 2009

Re: K091207
Trade Name: Surgicraft SURGILIG™ Acromioclavicular (AC) device
Dated: April 22, 2009
Received: April 24, 2009

Dear Mr. Guthner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require the following additional information:

(b) (4)



Page 2 – Mr. Donald W. Guthner

(b) (4)



Page 3 – Mr. Donald W. Guthner

(b) (4)



Page 4 – Mr. Donald W. Guthner

(b) (4)



We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the document titled “A Suggested Approach to Resolving Least Burdensome Issues” located at <http://www.fda.gov/cdrh/modact/leastburdensome.html>

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Act. You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations (21 CFR 812).

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from

Page 5 – Mr. Donald W. Guthner

our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k)(21 CFR 807.87(l)); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. For guidance on 510(k) actions, please see our guidance document entitled, "Guidance for Industry and FDA Staff: Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs, and BLA Supplements" at www.fda.gov/cdrh/ode/guidance/1655.html.

If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the additional information request.

The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at <http://www.fda.gov/cdrh/mdufma/guidance/1219.html>.

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to prior to July 31, 2009:

Food and Drug Administration
Center for Devices and
Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

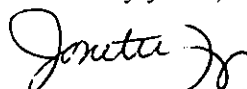
Documents that are to be received August 3, 2009 and after should be sent to the following address:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Page 6 – Mr. Donald W. Guthner

If you have any questions concerning the contents of the letter, please contact Ms. Elizabeth Frank at 240-276-3673 or elizabeth.frank@fda.hhs.gov. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (240) 276-3150, or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Jonette R. Foy, Ph.D.

Chief, Orthopaedic Joint Devices Branch
Division of Surgical, Orthopedic
and Restorative Devices
Center for Devices and
Radiological Health



Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

April 24, 2009

SURGICRAFT LTD.
C/O ORGENIX, LLC
111 HILL ROAD
DOUGLASSVILLE, PENNSYLVANIA 19518
UNITED STATES
ATTN: DONALD W. GUTHNER

510k Number: K091207

Received: 4/24/2009

Product: SURGICRAFT SURGILIG ACROMIOCLA

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. **YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.**

Please remember that all correspondence concerning your submission **MUST** be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at <http://www.fda.gov/cdrh/mdufma/index.html> for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at <http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf>.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form (<http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3674.pdf>) accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

Records processed under FOIA Request # 2015-684. Released by CDRH on 10-08-2015
Product, and Device Applications Submissions. Compliance with Section 402(j) of The Public Health Service Act,
Added By Title VIII of The Food and Drug Administration Amendments Act of 2007”

(http://www.fda.gov/oc/initiatives/fdaaa/guidance_certifications.html). According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

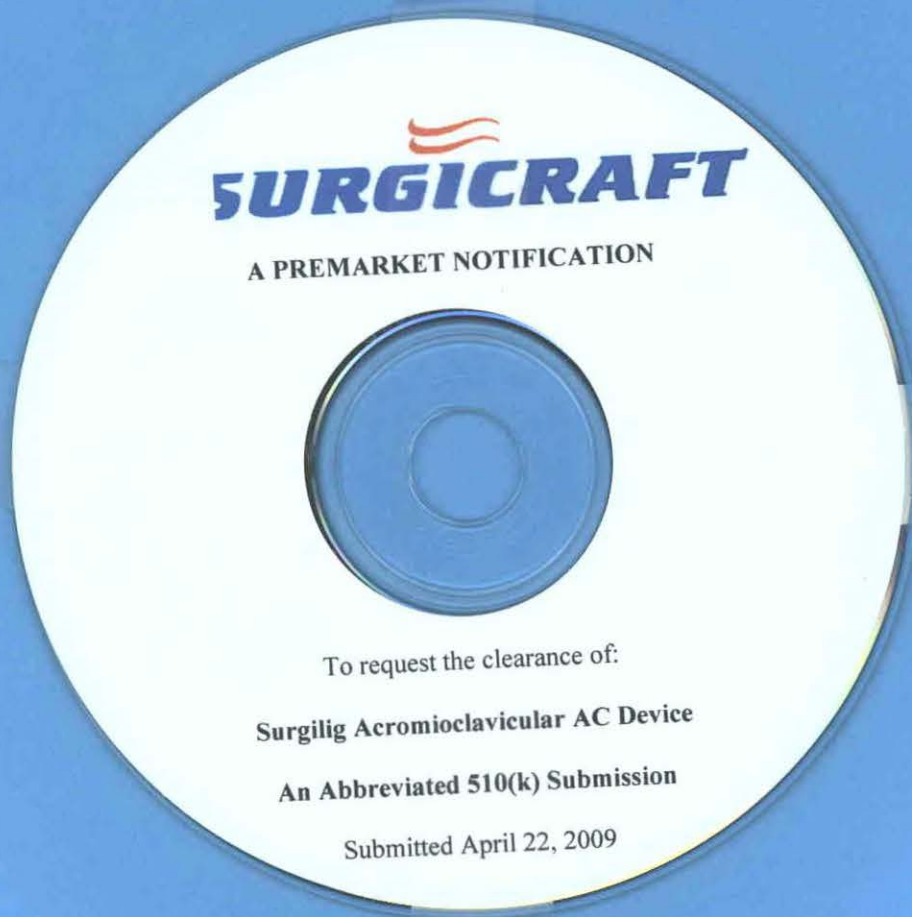
Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, “Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements”. This guidance can be found at <http://www.fda.gov/cdrh/ode/guidance/1655.pdf>. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at www.fda.gov/cdrh/electsub.html. In addition, the 510(k) Program Video is now available for viewing on line at www.fda.gov/cdrh/video/510k.wmv.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice www.fda.gov/cdrh/devadvice/". If you have questions on the status of your submission, please contact DSMICA at (240) 276-3150 or the toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsma/dsmastaf.html>. If you have procedural questions, please contact the 510(k) Staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health



2091207



April 22, 2009

FDA CDRH DMC

Office of Device Evaluation, 510(k)
Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

APR 24 2009

Received

RE: 510(k) Application – Surgicraft SURGILIG™ Acromioclavicular AC Device
Attn: Document Control Clerk

Orgenix, LLC is performing the role of consultant on behalf of:

Surgicraft Limited

and is requesting marketing clearance for its Surgicraft SURGILIG™ Acromioclavicular AC Device.

The premarket notification information required by 21 CFR 807.87 is as follows:

Classification Name: Single/Multiple component metallic bone fixation appliances and accessories
21 CFR 888.3030
Product Code: HTN
Orthopaedic Panel
Class II

Common/Usual Name: Bone fixation device

Proprietary Name(s): Surgicraft SURGILIG™ Acromioclavicular AC Device

Establishment Registration Number: 8020712

Contact Information:

Company (b) (6), Operations Director
Surgicraft, Ltd.
16 The Oaks
Clews Road
Redditch, England, B98 7ST
+44 1527 555880

(b) (6)

CRO Services - Regulatory * Clinical * Reimbursement
111 Hill Road * Douglassville, PA 19518
(646) 460-2984 * (888) ORGENIX * (484) 363-5879 (FAX)
www.orgenix.com

K24
OR
II

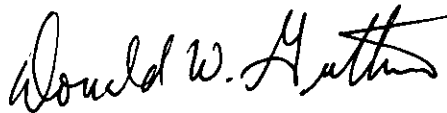
223

US Agent Donald W. Guthner
 Orgenix, LLC
 111 Hill Road
 Douglassville, PA 19518
 646-460-2984
 484-363-5879 (FAX)
 dg@orgenix.com

We consider our intent to market this device as confidential commercial information and request that it be considered as such by FDA.

We would appreciate FDA's earliest attention to this Section 510(k) submission.

Sincerely,



Donald W. Guthner
Principal
Orgenix, LLC

On behalf of
Surgicraft Ltd.



224



**Traditional
Pre-Market Notification 510(k)**

SURGILIG™ Acromioclavicular (AC) Device

Submitted by:

**Surgicraft (Trading Name of Mandaco 569)
16 The Oaks
Clews Road
Redditch
Worcestershire
B98 7ST
GB**

Official contact:

**Donald W. Guthner
Orgenix, LLC
111 Hill Road
Douglassville, PA 19518
(646) 460-2984
dg@orgenix.com**

Confidential

Surgicraft SURGILIG™
Acromioclavicular (AC) 510(k)

Confidential

Original

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION CDRH PREMARKET REVIEW SUBMISSION COVER SHEET			Form Approval OMB No. 9010-0120 Expiration Date: August 31, 2010. See OMB Statement on page 5.		
Date of Submission December 31, 2008		User Fee Payment ID Number		FDA Submission Document Number (if known)	
SECTION A TYPE OF SUBMISSION					
PMA <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement		PMA & HDE Supplement <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA & HDE Supplement <input type="checkbox"/> Other		PDP <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	
		510(k) <input checked="" type="checkbox"/> Original Submission: <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party		Meeting <input type="checkbox"/> Pre-510(K) Meeting <input type="checkbox"/> Pre-IDE Meeting <input type="checkbox"/> Pre-PMA Meeting <input type="checkbox"/> Pre-PDP Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Other (specify):	
IDE <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement		Humanitarian Device Exemption (HDE) <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment		Class II Exemption Petition <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	
		Evaluation of Automatic Class III Designation (De Novo) <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information		Other Submission <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):	
Have you used or cited Standards in your submission? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No (If Yes, please complete Section I, Page 5)					
SECTION B SUBMITTER, APPLICANT OR SPONSOR					
Company / Institution Name Surgicraft (Trading name of Mandaco 569)			Establishment Registration Number (if known) 8020712		
Division Name (if applicable)			Phone Number (including area code) +44.152.751.2624		
Street Address 16 The Oaks, Clews Road			FAX Number (including area code)		
City Redditch		State / Province	ZIP/Postal Code B98 7ST	Country UK	
Contact Name (b) (6)					
Contact Title Operations Director			Contact E-mail Address (b) (6)		

**Surgicraft SURGILIG™
Acromioclavicular (AC) 510(k)**

Confidential

Original

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)			
Company / Institution Name Orgenix, LLC			
Division Name (if applicable)		Phone Number (including area code) (646) 460-2984	
Street Address 111 Hill Road		FAX Number (including area code) (484) 363-5879	
City Douglasville	State / Province PA	ZIP/Postal Code 19518	Country USA
Contact Name Mr. Donald W. Guthner			
Contact Title Regulatory Consultant		Contact E-mail Address dg@orgenix.com	

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE		
<input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software / Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager
<input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Sterilization <input type="checkbox"/> Packaging <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment
<input type="checkbox"/> Response to FDA correspondence:		<input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address
<input type="checkbox"/> Other Reason (specify):		

Surgicraft SURGILIG™
Acromioclavicular (AC) 510(k)

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Original

SECTION D2	REASON FOR APPLICATION – IDE	
<input type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access Request for Removal of Applicant Hold	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent / Applicant <input type="checkbox"/> Design / Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol - Feasibility <input type="checkbox"/> Protocol - Other <input type="checkbox"/> Sponsor	<input type="checkbox"/> Repose to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing Manufacturer
<input type="checkbox"/> Other Reason (<i>specify</i>):		
SECTION D3	REASON FOR SUBMISSION - 510(k)	
<input checked="" type="checkbox"/> New Device	<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology
<input type="checkbox"/> Other Reason (<i>specify</i>):		

**Surgicraft SURGILIG™
Acromioclavicular (AC) 510(k)**

Confidential

Original

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed				Summary of, or statement concerning, safety and effectiveness information <input checked="" type="checkbox"/> 510 (k) summary attached <input type="checkbox"/> 510 (k) statement
1	HTN	2		
5		6		
		7		
		8		

Information on devices to which substantial equivalence is claimed (if known)

510(k) Number	Trade or Proprietary or Model Name	Manufacturer
1 K052776	1 TightRope	1 Arthrex
2 K072370	2 Surgical Mesh	2 Surgicraft
3 K080447	3 Screw Fixation System	3 Surgicraft
4 K963739	4 Luhr Small Orthopedic Bone Screw System	4 Howmedica - Leibinger

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification
Single/multiple component metallic bone fixation appliances and accessories

Trade or Proprietary or Model Name for This Device	Model Number
1 SURGILIG™ Acromioclavicular (AC) Device	1 See Device Description Section
2	2
3	3
4	4
5	5

FDA document numbers of all prior related submissions (regardless of outcome)

1 K072370	2 K080447	3	4	5	6
7	8	9	10	11	12

Data Included in Submission
 Laboratory Testing Animal Trials Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code HTN	C.F.R. Section (if applicable) 888.3030	Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel Orthopedic		

Indications (from labeling)
The Surgicraft SURGILIG™ Acromioclavicular (AC) device is indicated to provide fixation during the healing process following a syndesmotic trauma, such as fixation of acromioclavicular separations due to coracoclavicular ligament disruptions.

Surgicraft SURGILIG™
Acromioclavicular (AC) 510(k)

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Original

<i>Note:</i> Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.		FDA Document Number (if known)	
SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION			
<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	Facility Establishment Identifier (FEI) Number 8020712	<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name Surgicraft (Trading Name of Mandaco 569)		Establishment Registration Number 8020712	
Division Name (if applicable)		Phone Number (including area code) +44.152.751.2624	
Street Address 16 The Oaks, Clews Road		FAX Number (including area code)	
City Redditch	State / Province	ZIP/Postal Code B98 7ST	Country UK
Contact Name Steve Trotman	Contact Title Operations Director	Contact E-mail Address Steve.trotman@surgicraft.co.uk	
<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	Facility Establishment Identifier (FEI) Number	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input checked="" type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name (b) (4)		Establishment Registration Number	
Division Name (if applicable)		Phone Number (including area code) (b) (4)	
Street Address (b) (4)		FAX Number (including area code) (b) (4)	
City (b) (4)	State / Province	ZIP/Postal Code (b) (4)	Country (b) (4)
Contact Name (b) (4)	Contact Title (b) (4)	Contact E-mail Address (b) (4)	
<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	Facility Establishment Identifier (FEI) Number	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input checked="" type="checkbox"/> Repackager / Relabeler
Company / Institution Name (b) (4)		Establishment Registration Number (b) (4)	
Division Name (if applicable)		Phone Number (including area code) (b) (4)	
Street Address (b) (4)		FAX Number (including area code) (b) (4)	
City (b) (4)	State / Province	ZIP/Postal Code (b) (4)	Country (b) (4)
Contact Name (b) (4)	Contact Title (b) (4)	Contact E-mail Address (b) (4)	

Surgicraft SURGILIG™
Acromioclavicular (AC) 510(k)

Confidential

Original

SECTION I UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	F543	ASTM	Standard Specification and Test Methods for Metallic Medical Bone Screws		2007
2	5832-3:1996	ISO	Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI Alloy for Surgical Implant Applications		1998
3	5832-1:1997	ISO	Standard Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants		
4	10993	ISO	Biological evaluation of medical devices		2006
5					
6					
7					

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
CDRH (HFZ-342)
9200 Corporate Blvd.
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control

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Surgicraft SURGILIG™
Acromioclavicular (AC) 510(k)

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2. Administrative Documents

2.1 MDUFMA Payment

The MDUFMA User Fee has been paid. The User Fee Payment ID Number is:

(b) (4)



A copy of the receipt can be found in the Attachment 1.

2.2 FDA Form 3654 – Conformance to Standards

The FDA Form 3654 has been completed and can be found in the Attachment 1.

2.3 FDA Form 3674 – Clinical Trial Certification

The FDA Form 3674 has been completed and can be found in the Attachment 1. No data from a clinical trial is included in this submission.

3. Administrative Information

3.1 Manufacturer

Surgicraft (Trading Name of Mandaco 569)
16 The Oaks
Clews Road
Redditch, UK B98 7ST

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3.2 Submission Correspondent

Donald W. Guthner
Orgenix, LLC
111 Hill Road
Douglassville, PA 19518
Office: (646) 460-2984
Fax: (484) 363-5879
dg@orgenix.com

3.3 Device Information

Trade Name: SURGILIG™ Acromioclavicular (AC) Device

Device Type: Single/multiple component metallic bone fixation appliances and accessories.

3.4 Device Classification

Class: II

Classification: 888.3030

Classification Name: Single/multiple component metallic bone fixation appliances and accessories.

3.5 Product Code

HTN

4. Device Description

4.1 Design

The Surgicraft *SURGILIG™ Acromioclavicular (AC) device* is a combination of two FDA-cleared Surgicraft Products, the Surgicraft Surgical Mesh (K072370) and the Surgicraft Screw Fixation System (K080447). The new *SURGILIG™ Acromioclavicular (AC) device* will have a new indication to provide fixation during the healing process following a syndesmotic trauma, such as fixation of acromioclavicular separations due to coracoclavicular ligament disruptions.

The Surgicraft Surgical Mesh device is a woven mesh 11mm wide by 4 to 20 cm in length with loops at both ends. The Surgical Mesh is made from Polyester fibers (PET). Engineering Drawings of the Surgicraft *SURGILIG™ Acromioclavicular (AC) device* can be found in Attachment 2.

The *Surgicraft Screw Fixation System* is manufactured from stainless steel and titanium. The self-tapping 3.5 mm screws are available in lengths from 14- 40 mm in 1 mm increments. The washers have a hole with an inner diameter of 3.9 mm and an outer diameter ranging from 7 to 9 mm in 1 mm increments.

The Surgicraft *SURGILIG™ Acromioclavicular (AC) device* is provided sterile.

4.2 Instruments

Standard surgical instruments are used with the Surgicraft *SURGILIG™ Acromioclavicular (AC) device*

4.3 Materials

(b) (4)



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4.4 Device/Component Listing

The following device components are the subject of this 510(k).

Drawing Number	Part Number	Description	Sterile
	MSFS14	14mm Cortical Screw (3.5mm Dia) & 1mm Washer (SS)	Yes
	MSFS15	15mm Cortical Screw (3.5mm Dia) & 1mm Washer (SS)	Yes
	MSFS16	16mm Cortical Screw (3.5mm Dia) & 1mm Washer (SS)	Yes
	MSFS17	17mm Cortical Screw (3.5mm Dia) & 1mm Washer (SS)	Yes
	MSFS18	18mm Cortical Screw (3.5mm Dia) & 1mm Washer (SS)	Yes
	MSFS19	19mm Cortical Screw (3.5mm Dia) & 1mm Washer (SS)	Yes
	MSFS20	20mm Cortical Screw (3.5mm Dia) & 1mm Washer (SS)	Yes
	MSFS21	21mm Cortical Screw (3.5mm Dia) & 1mm Washer (SS)	Yes
	MSFS22	22mm Cortical Screw (3.5mm Dia) & 1mm Washer (SS)	Yes
	MSFS23	23mm Cortical Screw (3.5mm Dia) & 1mm Washer (SS)	Yes
	MSFS24	24mm Cortical Screw (3.5mm Dia) & 1mm Washer (SS)	Yes
	MSFS25	25mm Cortical Screw (3.5mm Dia) & 1mm Washer (SS)	Yes
	MSFS26	26mm Cortical Screw (3.5mm Dia) & 1mm Washer (SS)	Yes
	MSFS27	27mm Cortical Screw (3.5mm Dia) & 1mm Washer (SS)	Yes
	MSFS28	28mm Cortical Screw (3.5mm Dia) & 1mm Washer (SS)	Yes
	MSFS29	29mm Cortical Screw (3.5mm Dia) & 1mm Washer (SS)	Yes
	MSFS30	30mm Cortical Screw (3.5mm Dia) & 1mm Washer (SS)	Yes
	MSFS31	31mm Cortical Screw (3.5mm Dia) & 1mm Washer (SS)	Yes
	MSFS32	32mm Cortical Screw (3.5mm Dia) & 1mm Washer (SS)	Yes
	MSFS33	33mm Cortical Screw (3.5mm Dia) & 1mm Washer (SS)	Yes

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		Washer (SS)	
	MSFS34	34mm Cortical Screw (3.5mm Dia) & 1mm Washer (SS)	Yes
	MSFS35	35mm Cortical Screw (3.5mm Dia) & 1mm Washer (SS)	Yes
	MSFS36	36mm Cortical Screw (3.5mm Dia) & 1mm Washer (SS)	Yes
	MSFS37	37mm Cortical Screw (3.5mm Dia) & 1mm Washer (SS)	Yes
	MSFS38	38mm Cortical Screw (3.5mm Dia) & 1mm Washer (SS)	Yes
	MSFS39	39mm Cortical Screw (3.5mm Dia) & 1mm Washer (SS)	Yes
	MSFS40	40mm Cortical Screw (3.5mm Dia) & 1mm Washer (SS)	Yes
	MTFS14	14mm Cortical Screw (3.5mm Dia) & 1mm Washer (Ti)	Yes
	MTFS15	15mm Cortical Screw (3.5mm Dia) & 1mm Washer (Ti)	Yes
	MTFS16	16mm Cortical Screw (3.5mm Dia) & 1mm Washer (Ti)	Yes
	MTFS17	17mm Cortical Screw (3.5mm Dia) & 1mm Washer (Ti)	Yes
	MTFS18	18mm Cortical Screw (3.5mm Dia) & 1mm Washer (Ti)	Yes
	MTFS19	19mm Cortical Screw (3.5mm Dia) & 1mm Washer (Ti)	Yes
	MTFS20	20mm Cortical Screw (3.5mm Dia) & 1mm Washer (Ti)	Yes
	MTFS21	21mm Cortical Screw (3.5mm Dia) & 1mm Washer (Ti)	Yes
	MTFS22	22mm Cortical Screw (3.5mm Dia) & 1mm Washer (Ti)	Yes
	MTFS23	23mm Cortical Screw (3.5mm Dia) & 1mm Washer (Ti)	Yes
	MTFS24	24mm Cortical Screw (3.5mm Dia) & 1mm Washer (Ti)	Yes
	MTFS25	25mm Cortical Screw (3.5mm Dia) & 1mm Washer (Ti)	Yes
	MTFS26	26mm Cortical Screw (3.5mm Dia) & 1mm Washer (Ti)	Yes
	MTFS27	27mm Cortical Screw (3.5mm Dia) & 1mm Washer (Ti)	Yes
	MTFS28	28mm Cortical Screw (3.5mm Dia) & 1mm Washer (Ti)	Yes
	MTFS29	29mm Cortical Screw (3.5mm Dia) & 1mm Washer (Ti)	Yes

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		Washer (Ti)	
	MTFS30	30mm Cortical Screw (3.5mm Dia) & 1mm Washer (Ti)	Yes
	MTFS31	31mm Cortical Screw (3.5mm Dia) & 1mm Washer (Ti)	Yes
	MTFS32	32mm Cortical Screw (3.5mm Dia) & 1mm Washer (Ti)	Yes
	MTFS33	33mm Cortical Screw (3.5mm Dia) & 1mm Washer (Ti)	Yes
	MTFS34	34mm Cortical Screw (3.5mm Dia) & 1mm Washer (Ti)	Yes
	MTFS35	35mm Cortical Screw (3.5mm Dia) & 1mm Washer (Ti)	Yes
	MTFS36	36mm Cortical Screw (3.5mm Dia) & 1mm Washer (Ti)	Yes
	MTFS37	37mm Cortical Screw (3.5mm Dia) & 1mm Washer (Ti)	Yes
	MTFS38	38mm Cortical Screw (3.5mm Dia) & 1mm Washer (Ti)	Yes
	MTFS39	39mm Cortical Screw (3.5mm Dia) & 1mm Washer (Ti)	Yes
	MTFS40	40mm Cortical Screw (3.5mm Dia) & 1mm Washer (Ti)	Yes
RM04220-RM04240	Refer to drawing	14mm to 40mm Surgilig Cortical Screw (3.5mm Dia) (SS)	Yes
RM04220-RM04240	Refer to drawing	14mm to 40mm Surgilig Cortical Screw (3.5mm Dia) (Ti)	Yes
RM04082-RM04084	RM04082 RM04083 RM04084	7mm to 9mm Surgilig Washer (SS)	Yes
RM04082-RM04084	RM04085 RM04086 RM04087	7mm to 9mm Surgilig Washer (Ti)	Yes
RM03804-RM03820	SD6040	4cm Surgilig Mesh	Yes
RM03804-RM03820	SD6050	5cm Surgilig Mesh	Yes
RM03804-RM03820	SD6060	6cm Surgilig Mesh	Yes
RM03804-RM03820	SD6070	7cm Surgilig Mesh	Yes
RM03804-RM03820	SD6080	8cm Surgilig Mesh	Yes
RM03804-RM03820	SD6090	9cm Surgilig Mesh	Yes
RM03804-RM03820	SD6100	10cm Surgilig Mesh	Yes
RM03804-RM03820	SD6110	11cm Surgilig Mesh	Yes
RM03804-RM03820	SD6120	12cm Surgilig Mesh	Yes
RM03804-RM03820	SD6130	13cm Surgilig Mesh	Yes
RM03804-RM03820	SD6140	14cm Surgilig Mesh	Yes
RM03804-RM03820	SD6150	15cm Surgilig Mesh	Yes

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RM03804-RM03820	SD6160	16cm Surgilig Mesh	Yes
RM03804-RM03820	SD6170	17cm Surgilig Mesh	Yes
RM03804-RM03820	SD6180	18cm Surgilig Mesh	Yes
RM03804-RM03820	SD6190	19cm Surgilig Mesh	Yes
RM03804-RM03820	SD6200	20cm Surgilig Mesh	Yes

see A3
2/14/11
ELP

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5. Indications for Use

510(k) Number (if known): _____

Device Name: **Surgicraft SURGILIG™ Acromioclavicular (AC) device**

The Surgicraft *SURGILIG™ Acromioclavicular (AC) device* is indicated to provide fixation during the healing process following a syndesmotic trauma, such as fixation of acromioclavicular separations due to coracoclavicular ligament disruptions.

Prescription Use
 (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
 (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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A2 2/14/11
SCF

Surgicraft SURGILIG™
Acromioclavicular (AC) 510(k)

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6. 510(k) Summary

Contact: Donald W. Guthner
Orgenix, LLC
111 Hill Road
Douglassville, PA 19518
(646) 460-2984

Device Trade Name: SURGILIG™ Acromioclavicular (AC) device.

Manufacturer: Surgicraft (Trading Name of Mandaco 569)
16 The Oaks
Clews Road
Redditch, UK
B98 7ST

Classification: 21 CFR 888.3030, Single/multiple component metallic bone fixation appliances and accessories

Class: II

Product Code: HTN

Indications For Use:

The Surgicraft SURGILIG™ Acromioclavicular (AC) device is indicated to provide fixation during the healing process following a syndesmotic trauma, such as fixation of acromioclavicular separations due to coracoclavicular ligament disruptions.

Device Description:

The Surgicraft SURGILIG™ Acromioclavicular (AC) device is a combination of two FDA-cleared Surgicraft Products, the Surgicraft Surgical Mesh (K072370) and the Surgicraft Screw Fixation System (K080447). The new product is designated as the SURGILIG™ Acromioclavicular (AC) device and will have a new indication to provide fixation during the healing process following a syndesmotic trauma, such as fixation of acromioclavicular separations due to coracoclavicular ligament disruptions.

The Surgicraft Surgical Mesh device is a woven mesh 11mm wide by 4 to 20 cm in length with loops at both ends. The Surgical Mesh is made from braided Polyethyleneterephthalate (Polyester) fibers (PET).

The Surgicraft Screw Fixation System is manufactured from stainless steel and titanium alloy. The self-tapping 3.5 mm screws are available in lengths from 14- 40 mm in 1 mm increments. The washers have a hole with an inner diameter of 4.2 mm and an outer diameter ranging from 7 to 9 mm in 1 mm increments.

The Surgicraft SURGILIG™ Acromioclavicular (AC) device is provided sterile.

3015 A2
2/14/11 ELP

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Predicate Device(s):

The Surgicraft *SURGILIG™ Acromioclavicular (AC) device* was shown to be substantially equivalent to previously cleared devices and has the same indications for use, design, function, and/or materials.

Performance Standards:

Testing performed indicates the Surgicraft *SURGILIG™ Acromioclavicular (AC) device* is substantially equivalent to predicate devices.

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7. Product Characterization

The Sponsor has performed a number of tests to characterize the Surgicraft *SURGILIG™* Acromioclavicular (AC) Fixation device.

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8. Testing Summary

The following testing has been performed on the Surgicraft *SURGILIG™ Acromioclavicular (AC)* device:

- ASTM 543 - Standard Specification and Test Methods for Metallic Medical Bone Screws. The results were satisfactory for screw pullout. The complete report can be found in Attachment 4.
- Static Tension, Dynamic cyclic tensile testing, Mesh Burst Strength and Suture Attachment Strength on non-aged and aged material. Results were satisfactory and higher than physiological loads. The complete reports can be found in Attachment 4.

9. Biocompatibility

Surgicraft presented its data file on the Polyester material used in the Surgicraft *Surgical Mesh device* (K072370) to NAMSA for review and recommendations. NAMSA recommended a series of biological testing (ISO 10993 – 1) which was submitted to the FDA reviewer who agreed that the series of testing would be adequate to provide information on the biological acceptability of the Surgical Mesh. The FDA reviewer recommended that the muscle implantation study be increased from 2 weeks to 4, to which the Sponsor agreed.

Please find the following reports in Attachment 5:

(b)(4)



10. Substantial Equivalence Summary

The Surgicraft *SURGILIG™ Acromioclavicular (AC)* device is substantially equivalent in materials, indications, function and/or performance to the following predicate devices.

1. Arthrex TightRope (K052776)
2. Surgicraft Surgical Mesh device (K072370)
3. Surgicraft Screw Fixation System (K080447)
4. Howmedica-Leibinger Luhr Small Orthopedic Bone Screw System (K963739)

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Surgicraft believes the *SURGILIG™ Acromioclavicular (AC) device* is substantially equivalent to the Arthrex TightRope predicate based on indications, intended use and performance characteristics.

The *SURGILIG™ Acromioclavicular (AC) device* is manufactured from the same materials as Surgicraft's Screw Fixation System (Titanium or Stainless Steel) and Surgicraft's Surgical Mesh device (Polyester fibers). The sizes of the bone screw component of the *SURGILIG™ Acromioclavicular (AC) device* are encompassed by the range of screws available in the Howmedica-Leibinger Lurh® Small Orthopedic Bone Screw System, the smallest screw in the SURGILIG AC Device being a 3.5mm diameter 14mm long screw, the longest is a 3.5mm X 40mm screw.

A search of the MDR and MAUDE databases showed no reported incidences with these materials for this indication, indicating a certain level of safety of the product.

A table comparing the subject and predicate devices is presented below.

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Predicate Device Comparison

Information	Subject Device	Predicate Devices			
Manufacturer	Surgicraft	Arthrex	Surgicraft	Surgicraft	Howmedica - Leibinger
Trade Name	SURGILIG™ Acromioclavicular (AC) device	TightRope™ Acromioclavicular (AC) device	Screw Fixation System	Surgical Mesh	Luhr® Small Orthopedic Bone Screw System
510(k) Number	N/A	K052776	K080447	K072370	K963739
Product Code	HTN	HTN	HWC	FTL	HWC
Classification	888.3030	888.3030			
Materials	Titanium Alloy Stainless Steel Polyester (PET) fiber	Titanium Alloy UHMWPE Polyester	Titanium Alloy Stainless Steel	Polyester (PET) fiber	Titanium Alloy
Indications for Use	The Surgicraft <i>SURGILIG™ Acromioclavicular (AC) device</i> is indicated to provide fixation during the healing process following a syndesmotic trauma, such as fixation of acromioclavicular separations due to coracoclavicular ligament disruptions.	The TightRope™ Acromioclavicular (AC) Device is intended as an adjunct in fracture repair involving metaphyseal and periarticular small bone fragments where screws are not indicated, and as an adjunct in external and intramedullary fixation systems involving plates and rods, with fracture braces and casting. Specifically, the Arthrex TightRope Acromioclavicular (AC) Device is intended to provide fixation during the healing process following a syndesmotic trauma, such as fixation of acromioclavicular separations due to coracoclavicular ligament disruptions.	NA	NA	NA
Screws/Washers	Identical Screw diameter 3.5mm lengths 14mm to 40 mm		Identical Screw lengths 20mm to 40mm		Screw sizes from 0.8mm – 3.5mm diameter, 2.0mm to 40mm length
Surgical Mesh	Identical			Identical	

* Predicate Clearance Letters and 510(k) Summaries can be found in Attachment 9

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11. Packaging and Sterilization

The Surgicraft *SURGILIG™ Acromioclavicular (AC) device* is supplied sterile and is intended for single use only. The Surgicraft *SURGILIG™ Acromioclavicular (AC) device* is sterilized using the following processes:

The stages of manufacture for the Surgilig mesh are:

(b) (4)



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(b) (4)



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Packaging specifications and sterilization reports can be found in Attachment 6.

12.Shelf-life and Storage/Shipping Parameters

Product Expiration Dating.

(b)(4)



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13. Labeling and Package Insert

Proposed labeling can be found in Attachment 8.

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14. Truthful and Accurate Statement

A signed truthful and accurate statement follows this page.

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**PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT
(As Required By 21 CFR 807.87(k))**

I certify that, in my capacity as Operations Director of Surgicraft, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

(b) (6), Operations Director
Surgicraft

(b) (6)

A large rectangular grey box redacting the signature and name of the Operations Director.

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Acromioclavicular (AC) 510(k)

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15. Attachments

Attachment 1 – Regulatory Documents

MDUFMA Payment Sheet
FDA Form 3654 – Conformance to Standards
FDA Form 3674 – Clinical Trial Certification

Attachment 2 – Engineering Drawings

Attachment 3 – MSDS Sheets

Polyethyleneterephthalate (Polyester) fibers, PET

Attachment 4 – Mechanical Test Protocols and Reports

Attachment 5 – Biocompatibility Test Results

Attachment 6 – Packaging and Sterilization Validation Reports

Attachment 7 – Shelf-life Validation Protocol and Report

Attachment 8 – Labeling

Attachment 9 – Predicate Clearance Letters and 510(k) Summaries

ATTACHMENT 1
Regulatory Documents

Form Approved OMB No. 0910-511 Expiration Date January 31, 2010 See Instructions for OMB Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET		PAYMENT IDENTIFICATION NUMBER: (b) (4) Write the Payment Identification number on your check.			
A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/cover-sheet.html					
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) SURGICRAFT LIMITED 16 THE OAKS 16 The Oaks Clews Road Redditch Warwickshire B98 7ST GB 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) NO DATA		2. CONTACT NAME (b) (6) 2.1 E-MAIL ADDRESS (b) (6) 2.2 TELEPHONE NUMBER (include Area code) 01527 555887 2.3 FACSIMILE (FAX) NUMBER (Include Area code)			
3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma) Select an application type: <table border="0" style="width: 100%;"> <tr> <td style="width: 50%; vertical-align: top;"> <input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> Annual Fee for Periodic Reporting (APR) <input type="checkbox"/> 30-Day Notice </td> <td style="width: 50%; vertical-align: top;"> 3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER 3.2 Select one of the types below <input checked="" type="checkbox"/> Original Application Supplement Types: <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP) </td> </tr> </table>				<input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> Annual Fee for Periodic Reporting (APR) <input type="checkbox"/> 30-Day Notice	3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER 3.2 Select one of the types below <input checked="" type="checkbox"/> Original Application Supplement Types: <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)
<input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> Annual Fee for Periodic Reporting (APR) <input type="checkbox"/> 30-Day Notice	3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER 3.2 Select one of the types below <input checked="" type="checkbox"/> Original Application Supplement Types: <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)				
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <input type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input checked="" type="checkbox"/> NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number:					
5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA? <input checked="" type="checkbox"/> YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.) <input type="checkbox"/> NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)					
6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION. <table border="0" style="width: 100%;"> <tr> <td style="width: 50%; vertical-align: top;"> <input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only </td> <td style="width: 50%; vertical-align: top;"> <input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially </td> </tr> </table>				<input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only	<input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially
<input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only	<input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially				
7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA)). <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO					
8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (b) (4)		16-Mar-2009			

Form FDA 3041 (01/2007)

"Close Window" Print Cover sheet

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(b) (6)

From: paygovadmin@mail.doc.twai.gov
Sent: 16 March 2009 16:15
To: Robert Turner
Subject: Pay.Gov Payment Confirmation

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

Your transaction has been successfully completed.

Payment Summary

Application Name: FDA User Fees
Pay.gov Tracking ID: (b) (4)
Agency Tracking ID: (b) (4)

Account Holder Name: SURGICRAFT LIMITED
Transaction Type: Sale
Billing Address: 16 The Oaks
Billing Address 2: Clews Road
City: Redditch
Zip/Postal Code: B98 7ST
Country: GBR
Card Type: (b) (4)
Card Number: (b) (4)
Payment Amount: (b) (4)
Transaction Date: Mar 16, 2009 12:14:58 PM

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s
(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(k) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE

ASTM F543 Standard Specification and Test Methods for Metallic Medical Bone Screws 2002

Please answer the following questions

Yes No

Is this standard recognized by FDA? Yes No

FDA Recognition number #

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? Yes No

Is a summary report¹ describing the extent of conformance of the standard used included in the 510(k)? Yes No
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? Yes No

Does this standard include acceptance criteria? Yes No
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests? Yes No
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard? Yes No
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)²? Yes No

Were deviations or adaptations made beyond what is specified in the FDA SIS? Yes No
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard? Yes No
If yes, report these exclusions in the summary report table.

Is there an FDA guidance³ that is associated with this standard? Yes No
If yes, was the guidance document followed in preparation of this 510(k)? Yes No

Title of guidance:

¹ The formatting convention for the title is [SDC] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d]. www.fda.gov/cdrh/stdsprog.html
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

³ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or

certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

² The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

³ The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s
(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE¹

ISO 10993 Biological evaluation of medical devices - part 1, 2006

Please answer the following questions

Yes No

Is this standard recognized by FDA²?

FDA Recognition number³ #

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report⁴ describing the extent of conformance of the standard used included in the 510(k)?
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?
If yes, report these exclusions in the summary report table.

Is there an FDA guidance⁶ that is associated with this standard?
If yes, was the guidance document followed in preparation of this 510k?

Title of guidance:

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d]. www.fda.gov/cdrh/stdsprog.html

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or

certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁶ The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html



DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. NAME OF SPONSOR/APPLICANT/SUBMITTER Surgicraft	2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
3. ADDRESS (Number, Street, State, and ZIP Code) 8 Pagets Lane South Moons Moat Redditch, UK B98 0RA	4. TELEPHONE AND FAX NUMBER (Include Area Code) (Tel.) +44.152.751.2624 (Fax)

PRODUCT INFORMATION

5. **FOR DRUGS/BIOLOGICS:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s)
FOR DEVICES: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)
(Attach extra pages as necessary)

Surgicraft SURGIIIG (IM) Acromioclavicular (AC) device

APPLICATION / SUBMISSION INFORMATION

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

IND NDA ANDA BLA PMA HDE 510(k) PDP Other

7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER (If number previously assigned)

8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

CERTIFICATION STATEMENT / INFORMATION

9. CHECK ONLY ONE OF THE FOLLOWING BOXES (See instructions for additional information and explanation)

A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES (Attach extra pages as necessary)

NCT Number(s):

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.
Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign)	12. NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11 (Name) (b) (6) (Title) Operations Director
13. ADDRESS (Number, Street, State, and ZIP Code) (of person identified in No. 11 and 12) 8 Pagets Lane South Moons Moat Redditch, UK B98 0RA	14. TELEPHONE AND FAX NUMBER (Include Area Code) (Tel.) +44.152.751.2624 (Fax)
	15. DATE OF CERTIFICATION

ATTACHMENT 2
Engineering Drawings

Records processed under FOIA Request # 2015-684; Released by CDRH on 10-08-2015

Records processed under FOIA Request # 2015-684; Released by CDRH on 10-08-2015

Records processed under FOIA Request # 2015-684; Released by CDRH on 10-08-2015

ATTACHMENT 3
MSDS Sheets

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Records processed under FOIA Request # 2015-684; Released by CDRH on 10-08-2015

Records processed under FOIA Request # 2015-684; Released by CDRH on 10-08-2015

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ATTACHMENT 4
Mechanical Test Protocols and Reports

Records processed under FOIA Request # 2015-684; Released by CDRH on 10-08-2015

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ATTACHMENT 6
Packaging and Sterilization Validation Reports

436

Records processed under FOIA Request # 2015-684; Released by CDRH on 10-08-2015

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ATTACHMENT 7
Shelf-life Validation Protocol and Report

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ATTACHMENT 8
Labeling



A4

Surgilig™ Acromioclavicular (AC) Device

Instructions for Use

INDICATIONS

The Surgicraft Surliglig™ Acromioclavicular (AC) Device is intended to provide fixation during the healing process following a syndesmotie trauma, such as acromioclavicular separation, due to coracoclavicular ligament disruption.

CONTRAINDICATIONS

1. Insufficient quantity or quality of bone.
2. Blood supply limitations and previous infections, which may hinder healing.
3. Foreign-body sensitivity. Where material sensitivity is suspected, appropriate tests should be made and sensitivity ruled out prior to implantation.
4. Any active infection.
5. Conditions which tend to limit the patient's ability or willingness to restrict activities or follow directions during the healing period.
6. The use of this device may not be suitable for patients with insufficient or immature bone. The physician should carefully assess bone quality before performing orthopaedic surgery on patients who are skeletally immature. The use of this medical device and the placement of hardware or implants must not bridge, disturb, or disrupt the growth plate.
7. Do not use for surgeries other than those indicated.

ADVERSE EFFECTS

1. Infections, both deep and superficial.
2. Allergies and other reactions to device materials.

CAUTION

Federal Law (U.S.A.) restricts Surliglig™ Acromioclavicular (AC) Device to sale by or on the order of a physician. Only physicians qualified in appropriate surgical technique should use this device.

WARNINGS

1. All metal implants used for this surgical procedure must have the same metallurgical composition.
2. Postoperatively, until healing is complete the fixation provided by this device should be protected. The postoperative regimen prescribed by the physician should be strictly followed to avoid adverse stress to the implant.
3. Detailed instructions on the use and limitations of the device should be given to the patient.
4. Any decision to remove the device should take into consideration the potential risk to the patient of a second surgical procedure. Implant removal should be followed by adequate postoperative management.
5. Preoperative and operating procedures, including knowledge of surgical techniques and proper selection and placement of the implant, are important considerations in the successful utilisation of this device.
6. An internal fixation device must never be reused.
7. Do not re-sterilise this device.
8. The appropriate Surgicraft instrumentation is required for proper insertion of the implant.
9. Once open, discard any unused device.

Manufactured by:

Surgicraft (Trading name of Mandaco 569) / 16 The Oaks / Clews Road / Redditch / Worcestershire / B98 7ST / UK
T: +44 1527 512600 / F: +44 1527 512612 / E: info@surgicraft.co.uk / www.surgicraft.co.uk

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SURGICRAFT

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PACKAGING AND LABELING

1. Surgicraft implants should be accepted only if the factory packaging and labelling arrive intact.
2. Contact Customer Service if package has been opened or altered.

STERILISATION

The Surgilig™ Acromioclavicular (AC) Device has been sterilised with Gamma Irradiation. Provided that the integrity of the package is not compromised in any way, the package will serve as an effective barrier for 5 years from the date of sterilisation. There is a 5 year expiration date for product function or characteristics. This is a single use device and should not be re-sterilised. Surgicraft instruments, which should be used during this procedure, are provided non-sterile and must be adequately cleaned and sterilised prior to use or re-use.

MATERIAL SPECIFICATIONS

Surgilig™ Acromioclavicular (AC) Device: Stainless Steel Screw and Washer to ISO5832-1 or Titanium Alloy Screws and Washer to ISO5832-3.

Surgilig™ Mesh: Polyethyleneterephthalate, ie Polyester Fibres (PET)

STORAGE CONDITIONS

The Surgilig™ Acromioclavicular (AC) Device must be stored in the original unopened packaging, away from moisture and should not be used after the expiration date.

INFORMATION

For more information, or a demonstration, contact your local Surgicraft representative.

DIRECTIONS FOR USE

Users of these devices are encouraged to contact their Surgicraft representatives if, in their professional judgment, they require a more comprehensive surgical technique.

SURGILIG™ ACROMIOCLAVICULAR (AC) DEVICE: Surgical Technique

1. The lateral end of the clavicle is exposed and the base of the coracoid identified via a shoulder strap incision.
2. 1cm of the lateral end of the clavicle is excised in the plane of the acromioclavicular joint.
3. The Tubular Introducer is passed around the base of the coracoid from medial to lateral, staying close to the bone.
4. The metal leader of the Length Gauge is passed through the Tubular Introducer from medial to lateral.
5. The Tubular Introducer is removed leaving the Length Gauge around the base of the coracoid.
6. The metal leader of the Length Gauge is passed through the loop at the other end of the Length Gauge removing any slack.
7. The metal leader of the Length Gauge is passed under the lateral end of the clavicle from anterior to posterior.

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SURGICRAFT

See A4

8. The clavicle is reduced to its anatomical position and the Length Gauge is held in the planned position of the Surgilig™ Cortical Screw and Washer to measure the required Surgilig™ Mesh length.

Note: The markings on the Length Gauge are 1cm apart. The double stitch represents an 11cm Surgilig™ Mesh.

9. The metal leader is passed back under the clavicle and back through its loop to undo the anchorage point. The Length Gauge is NOT removed from under the coracoid.
10. The soft loop of the Length Gauge is passed through the hard loop of the chosen Surgilig™ Mesh.
11. The soft loop of the Length Gauge is then passed over the soft loop of the Surgilig™ Mesh.
12. The soft loop of the Length Gauge is then pulled down the length of the Surgilig™ Mesh securing itself to the hard loop.
13. The Surgilig™ Mesh is passed under the coracoid, by pulling the Length Gauge.
14. The metal leader of the Length Gauge is passed through the soft loop of the Surgilig™ Mesh, positioning the Surgilig™ Mesh around the base of the coracoid. Any slack is removed using the Loop Tensioner.
15. Using the metal leader as a guide, the Length Gauge is passed under the clavicle and the Surgilig™ Mesh is tensioned across the superior aspect of the clavicle and the clavicle reduced.

16. The hard loop is anchored to the anterior clavicle using the Surgilig™ Cortical Screw and Washer. The clavicle is prepared for the Surgilig™ Cortical Screw and Washer using a drill and tap.

Note: The Surgilig™ Cortical Screw and Washer should be inserted at an angle to avoid possible abrasion of the Surgilig™ Mesh by the Screw tip.

17. Add an additional 4mm to the measured Surgilig™ Cortical Screw length, to allow for the height of the washer and ensure bicortical fixation. The Surgilig™ Cortical Screw and Washer are seated into place.

Note: Cut the Length Gauge from the hard loop of the Surgilig™ Mesh before the Surgilig™ Cortical Screw and Washer are fully seated.

18. All soft tissue is reconstructed over the top of the clavicle and acromioclavicular joint, and the wound closed in layers. The arm is supported for 2 weeks in a polysling and the patient is advised against heavy lifting for 3 months. Rehabilitation should progress at the surgeon's discretion.

SUGGESTED INSTRUCTIONS FOR USING SURGILIG™ ACROMIOCLAVICULAR (AC) DEVICE:

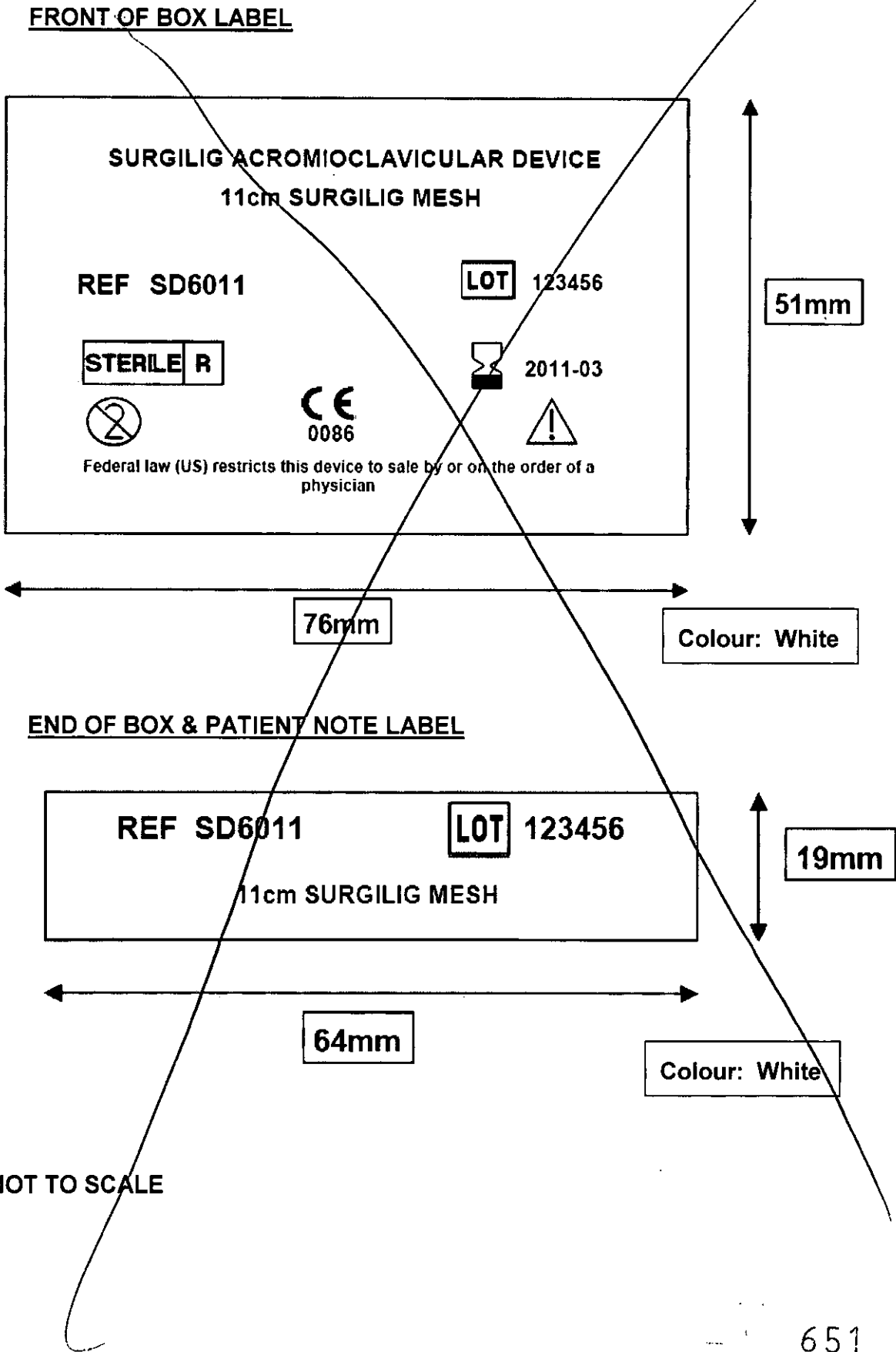
The recommend surgical technique above is designed to serve as a general guideline. It is not intended to supersede institutional protocols or professional clinical judgment concerning patient care.

Manufactured by:

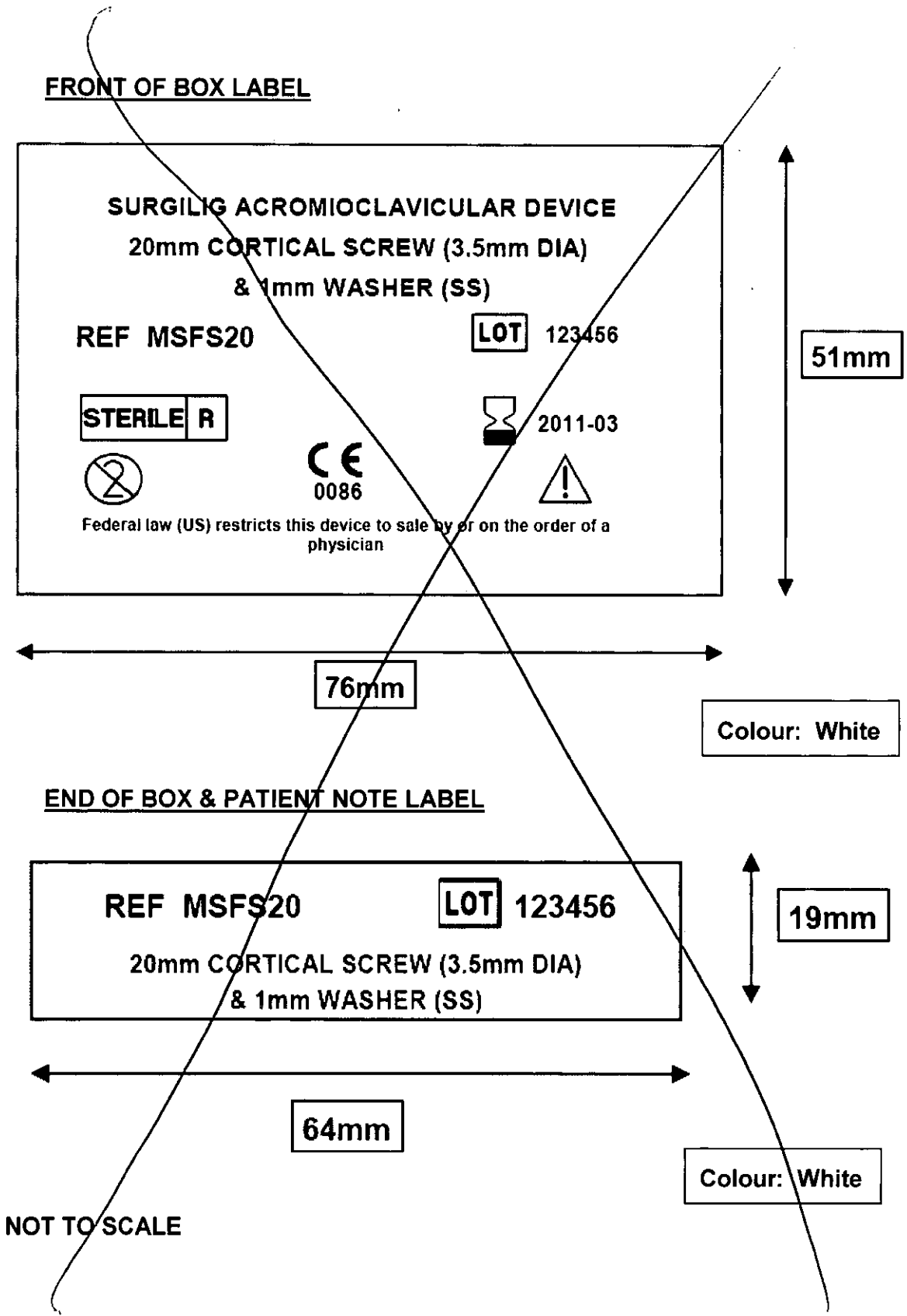
Surgicraft (Trading name of Mandaco 569) / 16 The Oaks / Clews Road / Redditch / Worcestershire / B98 7ST / UK
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ATTACHMENT 9
Predicate Clearance Letters and 510(k) Summaries

DEC 13 2005

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**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
TightRope™ Acromioclavicular (AC) Device**

NAME OF SPONSOR: Arthrex, Inc.
1370 Creekside Boulevard
Naples, Florida 34108-1945

510(K) CONTACT: Sally Foust, RAC
Regulatory Affairs Project Manager
Telephone: (239) 643-5553 ext. 1251
FAX: (239) 598-5539

TRADE NAME: TightRope™ Acromioclavicular (AC)
Device

COMMON NAME: Button/Suture

DEVICE PRODUCT CODE/CLASSIFICATION:

HTN: Single/multiple component
metallic bone fixation appliances and
accessories:
21 CFR 888.3030

PREDICATE DEVICES

K043248: TightRope Syndesmosis Device (Arthrex, Inc.)
K023294: Bosworth Coraco-Clavicular Screw and Washer (Howmedica
Osteonics)
K041356: Tenodesis Family (Arthrex, Inc.)
K003227: Bio-Absorbable Corkscrew (Arthrex, Inc.)
pre-1976, Kirschner (K) Wire (Synthes)

DEVICE DESCRIPTION AND INTENDED USE

The TightRope™ Acromioclavicular (AC) Device is designed as two differently sized metal buttons, both stainless steel or both titanium, and FiberWire™ suture. The buttons are pre-threaded with FiberWire suture, looped twice through the buttonholes. Pull-through FiberWire sutures are also looped through each button.

The TightRope™ Acromioclavicular (AC) Device is intended as an adjunct in fracture repair involving metaphyseal and periarticular small bone fragments where screws are not indicated, and as an adjunct in external and intramedullary fixation systems involving plates and rods, with fracture braces and casting.

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Specifically, the Arthrex TightRope Acromioclavicular (AC) Device is intended to provide fixation during the healing process following a syndesmotic trauma, such as fixation of acromioclavicular separations due to coracoclavicular ligament disruptions.

SUBSTANTIALLY EQUIVALENCE

Arthrex has determined that the TightRope™ Acromioclavicular (AC) Device is substantially equivalent to the predicate devices where basic features and intended uses are the same. Any design differences between the Arthrex TightRope™ Acromioclavicular (AC) Device when compared to predicate devices used in the standard medical practice for the treatment of acromioclavicular separations due to coracoclavicular disruptions are considered minor and do not raise any questions concerning safety and effectiveness. Any differences have been found to have no apparent effect on the performance, function, or intended use of the device.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Sally Foust, RAC
Regulatory Affairs Project Manager
Arthrex, Inc.
1370 Creekside Boulevard
Naples, Florida 34108-1945

DEC 13 2005

Re: K052776

Trade/Device Name: TightRope™ Acromioclavicular (AC) Device
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation
appliances and accessories
Regulatory Class: II
Product Code: HTN
Dated: September 28, 2005
Received: October 3, 2005

Dear Ms. Foust:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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Page 2 – Sally Foust, RAC

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



for Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

657

Indications for Use

510(k) Number (if known): K052776

Device Name TightRope™ Acromioclavicular (AC) Device

Indications for Use:

The TightRope™ Acromioclavicular (AC) Device is intended as an adjunct in fracture repair involving metaphyseal and periarticular small bone fragments where screws are not indicated, and as an adjunct in external and intramedullary fixation systems involving plates and rods, with fracture braces and casting.


Specifically, the Arthrex TightRope Acromioclavicular (AC) Device is intended to provide fixation during the healing process following a syndesmotic trauma, such as fixation of acromioclavicular separations due to coracoclavicular ligament disruptions.

Prescription Use AND/OR Over-The-Counter Use
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K052776

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K080447 (pg. 1 of 3)

SURGICRAFT

JUN 18 2008

510 (k) Summary

- A 510(k) Owner** Surgicraft Limited
16 The Oaks
Clews Road
Redditch, Worcester
England B98 7ST
- Contact** Donald W. Guthner
Orgenix, LLC
111 Hill Road
Douglassville, PA 19518
(888) ORGENIX
(484) 363-5879 (FAX)
dg@orgenix.com
- Preparation Date** February 18, 2008
- B Trade Name** Surgicraft Screw Fixation System
- Common Name** Fixation Bone Screw and Washer
- Classification Name** 21 CFR 888.3040
MBI
Smooth or threaded metallic bone fixation fastener
Class II
- C Predicate Device(s)** The subject device is substantially equivalent to similar previously cleared devices. Substantial equivalence for the *Surgicraft Screw Fixation System* is based on its similarities in indications for use, design features, operational principles and material composition when compared to the predicate devices cleared under the following submissions:
- ◆ K043185 – Stryker 3.5mm Cortex Screws
 - ◆ K071157 - Stryker Titanium Intraline Anchor
 - ◆ K973775 - Biomet Harpoon Suture Anchors
 - ◆ K012572 – Biomet Soft Tissue Screws and Washers

Surgicraft Limited / 16 The Oaks / Clews Road / Redditch / Worcestershire / UK / B98 7ST

Tel: +44 (0)1527 512600 / Fax: +44 (0)1527 551166 / Customer Service Fax: +44 (0)1527 512612 / E-mail: info@surgicraft.co.uk

www.surgicraft.co.uk

App. 2 - 2

K080447 (pg. 2 of 3)

- D Device Description The *Surgicraft Screw Fixation System* is manufactured from stainless steel and titanium. The self-tapping 3.5 mm screws are available in lengths from 20- 40 mm in 1 mm increments. The washers have an inner hole diameter of 4.2 mm and an outer diameter ranging from 7 to 9 mm in 1 mm increments.
- E Intended Use The *Surgicraft Screw Fixation System* is a single-use, soft tissue anchor which will be used to secure soft tissue to bone during reconstructive surgery. The anchor is intended for use in such procedures as:
- Shoulder:**
- * Rotator Cuff Repair
 - * Bankart Repair
 - * SLAP Lesion Repair
 - * Acromio-Clavicular Separation Repair
 - * Capsular Shift/Capsulolabral Reconstruction
 - * Biceps Tenodesis
 - * Deltoid Repair.
- Elbow. Wrist. Hand:**
- * Scapholunate Ligament Reconstruction
 - * Ulnar Collateral Ligament Reconstruction
 - * Radial Collateral Ligament Reconstruction
 - * Biceps Tendon Reattachment.
- Foot and Ankle:**
- * Medial Instability Repair/Reconstruction
 - * Lateral Instability Repair/Reconstruction
 - * Achilles Tendon Repair/Reconstruction
 - * Midfoot Reconstruction
 - * Hallux Valgus Reconstruction.
- Knee:**
- * Extra Capsular Repairs
 - o Medial Collateral Ligament
 - o Lateral Collateral Ligament
 - o Posterior Oblique Ligament
 - * Iliotibial Band Tenodesis
 - * Patellar Tendon Repair.
- Pelvis:**
- *Bladder Neck Suspension Procedures.
- F Technological Characteristics As was established in this submission, the subject device is substantially equivalent to other devices cleared by the agency for commercial distribution in the United States.
- Engineering drawings, labeling, and mechanical testing have

App. 2 - 3

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K080447 (pg. 3 of 3)

demonstrated that the subject device is substantially equivalent, if not identical, to its predicate devices in terms of design, materials of composition, indications for use, and such other characteristics as may be associated with the manufacture of any medical device.

- | | | |
|---|------------------------|---|
| G | Non-Clinical Testing | The <i>Surgicraft Screw Fixation System</i> was tested as follows: <ul style="list-style-type: none">• <u>Mechanical Testing</u>
ASTM – F543 - Standard Specification and Test Methods for Metallic Medical Bone Screws |
| H | Clinical Testing | Not applicable to this device |
| I | Conclusions | Based on the 510(k) Summary and the information provided herein, we conclude that the <i>Surgicraft Screw Fixation System</i> is substantially equivalent to the existing legally marketed devices under the Federal Food, Drug and Cosmetic Act. |
| J | Additional Information | No additional information |

App. 2 - 4

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Surgicraft, Ltd.
% Mr. Donald W. Guthner
Orgenix, LLC
111 Hill Road
Douglassville, Pennsylvania 19518

JUN 13 2008

Re: K080447

Trade/Device Name: Surgicraft Screw Fixation System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: MBI
Dated: May 13, 2008
Received: May 14, 2008

Dear Mr. Guthner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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Page 2 – Mr. Donald W. Guthner

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

663

Indications for Use

510(k) Number (if known): K080447

Device Name: Surgicraft Screw Fixation System

Indications for Use:

The *Surgicraft Screw Fixation System* and is a single-use, soft tissue anchor which will be used to secure soft tissue to bone during reconstructive surgery. The anchor is intended for use in such procedures as:

Shoulder:

- * Rotator Cuff Repair
- * Bankart Repair
- * SLAP Lesion Repair
- * Acromio-Clavicular Separation Repair
- * Capsular Shift/Capsulolabral Reconstruction
- * Biceps Tenodesis
- * Deltoid Repair.

Foot and Ankle:

- * Medial Instability Repair/Reconstruction
- * Lateral Instability Repair/Reconstruction
- * Achilles Tendon Repair/Reconstruction
- * Midfoot Reconstruction
- * Hallux Valgus Reconstruction.

Elbow, Wrist, Hand:

- * Scapholunate Ligament Reconstruction
- * Ulnar Collateral Ligament Reconstruction
- * Radial Collateral Ligament Reconstruction
- * Biceps Tendon Reattachment.

Knee:

- * Extra Capsular Repairs
 - o Medial Collateral Ligament
 - Lateral Collateral Ligament
 - Posterior Oblique Ligament
- * Iliotibial Band Tenodesis
- * Patellar Tendon Repair.

Pelvis:

- *Bladder Neck Suspension Procedures.
Single patient use only

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R.P. Ogle Sr. M.D.
 (Division Sign-Off)
 Division of General, Restorative,
 and Neurological Devices

Page 1 of 1

510(k) Number K080447

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4-2



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 7 2008

Surgicraft Ltd.
% Orgenix, LLC
Mr. Donald W. Guthner
111 Hill Road
Douglassville, Pennsylvania 19518

Re: K072370

Trade/Device Name: Surgicraft Surgical Mesh System
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: July 30, 2008
Received: July 31, 2008

Dear Mr. Guthner:

This letter corrects our substantially equivalent letter of July 24, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

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Att. 9 - 12

Page 2 – Mr. Donald W. Guthner

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Att. 9 - 13

K072370

Indications for Use

510(k) Number (if known): K072370

Device Name: Surgicraft Surgical Mesh System

Indications For Use:

The Surgicraft Surgical Mesh is intended for the reinforcement of the soft tissues which are repaired by suture or suture anchors during rotator cuff repair surgery.

The mesh is not intended to replace normal body structure or provide full mechanical strength to support the rotator cuff. Sutures used to repair the tear, and sutures or bone anchor systems used to attach the tissue to the bone, provide mechanical strength for tendon repair.

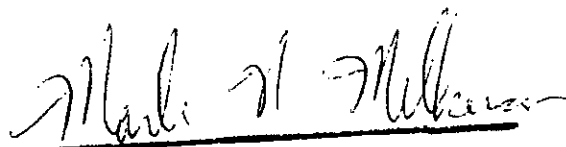
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K072370

K96 3739

510(k) Summary

JAN 22 1997

Device Proprietary Name: Leibinger[®] - Luhr[®] Small Orthopedic Bone Screw System

Device Common Name: Small Bone Screws

Classification Name: Single/Multiple Component Metallic Bone Fixation Appliances and Accessories 888.3030

Name of Submitter: Howmedica Leibinger Inc.

Contact Person (s): Andrew B. Rogers
Director, Product Development and Special Projects
Howmedica Leibinger Inc.
14540 Beltwood Pkwy. East
Dallas, TX 75244
Telephone: (214) 392-3636 x233
Fax: (214) 392-7258

Kristyn R. Waski
Product Engineer, Special Projects
Howmedica Leibinger Inc.
14540 Beltwood Pkwy. East
Dallas, TX 75244
Telephone: (214) 392-3636 x266
Fax: (214) 392-7258

Date Prepared: September 12, 1996

Summary:

This submission describes a system of small bone screws. It is intended for use in internal fixation of small bones including the hand and foot secondary to trauma or for reconstruction. Screws are available in diameters ranging from 0.8 to 3.5 mm and lengths ranging from 2 mm to 40 mm. These devices are for single use only.

Equivalence for this device is based on similarities in intended use, material, design and operational principle to the Howmedica Luhr[®] Fixation System (K761228, K882454, K913355, K935448); the Wurzburg[®] Bone Screws (K854886); the Steinhauser[®] Bone Screws (K862482) and the Howmedica Leibinger Forefoot Reconstruction System (K961485). The Luhr[®], Wurzburg[®] and Steinhauser[®], Profyle and Forefoot bone screws are intended for use as small bone screws in internal fixation procedures. The Forefoot screws are manufactured from Ti6Al4V. The basic operational principle is similar for each of these devices.

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COVER SHEET MEMORANDUM

From: Reviewer Name Elizabeth Frank
Subject: 510(k) Number K091207/S1
To: The Record

Please list CTS decision code SE

- Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)
- Hold (Additional Information or Telephone Hold).
- Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU	✓	
510(k) Summary /510(k) Statement	Attach Summary	✓	
Truthful and Accurate Statement.	Must be present for a Final Decision	✓	
Is the device Class III?			✓
If yes, does firm include Class III Summary?	Must be present for a Final Decision		✓
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		✓	
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)			✓
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			✓
Is this device intended for pediatric use only?			✓
Is this a prescription device? (If both prescription & OTC, check both boxes.)		✓	
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?		✓	
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If not, then applicant must be contacted to obtain completed form.)			✓
Does this device include an Animal Tissue Source?			✓
All Pediatric Patients age ≤ 21			✓
Neonate/Newborn (Birth to 28 days)			✓
Infant (29 days - < 2 years old)			✓
Child (2 years - < 12 years old)			✓
Adolescent (12 years - < 18 years old)			✓
Transitional Adolescent A (18 - < 21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing; different protocol procedures, etc.)			✓

Transitional Adolescent B (18 <= 21; No special considerations compared to adults => 21 years old)	✓
Nanotechnology	✓
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	Contact OC. ✓

Regulation Number	Class*	Product Code
888.3030	II	ATN

(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review: _____
(Branch Chief) *JDB* 2/15/11
(Branch Code) (Date)

Final Review: _____
(Division Director) *[Signature]* 2/15/11
(Date)



DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Review
Traditional

K091207/S001

Date: February 14, 2011

To: The Record

From: Elizabeth Frank, MS, Biomedical Engineer

Office: ODE

Division: DSORD/OJDB

510(k) Holder: Surgicraft, Ltd.

Device Name: Surgicraft LockDown™ Acromioclavicular (AC) Device

Contact: Mr. Donald W. Guthner

Orgenix, LLC

111 Hill Road

Douglasville, PA 19518

Phone: 646-460-2984

Fax: 484-363-5879

Email: dg@orgenix.com

Handwritten signature of Donald W. Guthner

I. Purpose and Submission Summary

The 510(k) holder would like to introduce the Surgicraft LockDown™ Acromioclavicular (AC) Device into interstate commerce. The Surgicraft™ LockDown™ Acromioclavicular (AC) device is a combination of two FDA-cleared Surgicraft Products, the Surgicraft Surgical Mesh (K072370) and the Surgicraft Screw Fixation System (K080447). The LockDown™ Acromioclavicular (AC) device will have a new indication to provide fixation during the healing process following a syndesmotic trauma, such as fixation of acromioclavicular separations due to coracoclavicular ligament disruptions. In Supplement 1, the sponsor changed the device name from SURGILIG to LockDown Acromioclavicular Device since SURGILIG implies ligament. The Surgicraft Surgical Mesh device is a woven mesh 11mm wide by 4 to 20 cm in length with loops at both ends. The Surgical Mesh is made from Polyethyleneterephthalate (i.e. Polyester fibers (PET)). The Surgicraft Screw Fixation System is manufactured from stainless steel 316L and titanium alloy 6Al4V ELI. The self-tapping 3.5mm screws are available in lengths from 14-40mm in 1mm increments. The washers have a hole with an inner diameter of 3.9mm and an outer diameter ranging from 7 to 9mm in 1mm increments.

The device is substantially equivalent to the Arthrex TightRope® Acromioclavicular device (K052776), which uses Polyethyleneterephthalate (Polyester) fibers (PET), stainless steel and titanium materials to fixate acromioclavicular separations. The biggest design difference between the two devices is the TightRope device is a suture looped through twice, while the subject device is a woven mesh. The woven mesh is stronger, but allows for tissue ingrowth. The sponsor has removed all references to tissue ingrowth from the submission.

Both devices have the same indications of "to provide fixation during the healing process following a syndesmotic trauma, such as fixation of acromioclavicular separations due to coracoclavicular ligament disruptions". Both devices include contraindications that the devices are "not intended to be used as the sole means of reconstructing a chronic acromioclavicular joint dislocation". The sponsor has provided a revised package insert (Amendment 4 dated February 14, 2011) and surgical

technique guide including this contraindication (Amendment 2 dated February 10, 2011). In Amendment 3, dated February 14, 2011 the sponsor provided a revised Indications for Use page with the device name "LockDown."

The sponsor's original submission made several references to the device being used as "a synthetic ligament used in acromion-clavicular reconstruction to replace the ligament and recreate the anatomy". The sponsor has modified the device name to the *LOCKDOWN™* Acromioclavicular (AC) device and included the appropriate contraindication that the device is not used as the sole means of reconstructing a chronic AC joint dislocation. The surgical technique guide shows the LockDown device being used in parallel between the AC ligaments, not replacing either one. In addition, there are several legally marketed predicate devices with similar designs and the same intent.

The sponsor provided comprehensive characterization data on the screw and mesh. The 14mm and 20mm screws were evaluated for pullout resistance and torsional strength. The mesh was evaluated for static and dynamic tensile stresses, burst strength, elongation and suture pullout strength. The sponsor has adequately characterized the screws and mesh, in addition to the construct as a whole through cadaver testing. Based on the similarities in design, indications for use, material and characterization testing, the subject device is **Substantially Equivalent (SE)** to the Arthrex Tightrope (K052776). The sponsor has clearly included a contraindication that the device is "not intended to be used as the sole means of reconstructing a chronic acromioclavicular joint dislocation."

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	X		
Truthful and Accuracy Statement	X		
510(k) Summary or 510(k) Statement	X		
Standards Data Report for 510(k)s (Form 3654)	X		
Clinical Trials Form (Form 3674)	X		

The Standards Forms and Clinical Trials Form are included in Attachment 1

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?	X		
Does the device design use software?		X	
Is the device sterile?	X		
Is the device reusable (not reprocessed single use)? Are "cleaning" instructions included for the end user?		X	

The Surgicraft™ *LockDown™* Acromioclavicular (AC) device is a combination of two cleared Surgicraft Products, the Surgicraft Surgical Mesh (K072370) and the Surgicraft Screw Fixation System (K080447). The new *LockDown™* Acromioclavicular (AC) device will have a new indication to provide fixation during the healing process following a syndesmotic trauma, such as fixation of acromioclavicular separations due to coracoclavicular ligament disruptions.

(b)(4)



(b)(4)



IV. Indications for Use

The Surgicraft *LockDown*TM Acromioclavicular (AC) device is indicated to provide fixation during the healing process following a syndesmotic trauma, such as fixation of acromioclavicular separations due to coracoclavicular ligament disruptions.



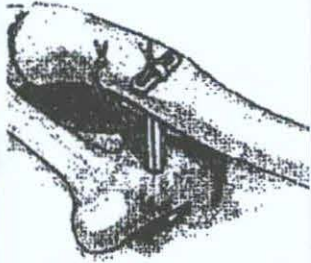
Reviewer Comment: The indications for use are identical to the indications for the TightRopeTM Acromioclavicular (AC) device (K052776) and the Smith & Nephew Ultraslide Acromioclavicular and Syndesmotic Repair Device (K082095). The sponsor has added the same contraindication as included for the TightRope to the package insert and surgical technique guide that "It is not intended that this technique be used as the sole means of reconstructing a chronic acromioclavicular joint dislocation." The sponsor provided a revised Indications for Use page with the device name LockDown in Amendment 3 dated February 14, 2011.

V. Predicate Device Comparison

The sponsor provides a predicate device comparison in Table 4.

Table 4: Predicate Device Comparison

Manufacturer	Surgicraft	Arthrex	Smith & Nephew	Surgicraft	Surgicraft	Howmedica-Leibinger
Device Name	LockDown™ Acromioclavicular (AC) device	TightRope™ Acromioclavicular (AC) device	Ultraslide Acromioclavicular and Syndesmotic Repair Device	Screw Fixation System	Surgical Mesh	Luhr® Small Orthopedic Bone Screw System
510(k) Number	Subject	K052776	K082095	K080447	K072370	K963679
Product Code	HTN	HTN	HTN	HWC	FTL	HWC
Materials	Titanium Alloy Stainless Steel Polyester (PET) fiber	Titanium Alloy UHMWPE Polyester	Titanium Alloy Polyester	Titanium Alloy Stainless Steel	Polyester (PET) Fiber	Titanium Alloy
Indications for Use	The Surgicraft LockDown™ Acromioclavicular (AC) device is indicated to provide fixation during the healing process following a syndesmotic trauma, such as fixation of acromioclavicular separations due to coracoclavicular ligament disruptions.	The TightRope™ Acromioclavicular (AC) Device is intended as an adjunct in fracture repair involving metaphyseal and periarticular small bone fragments where screws are not indicated, and as an adjunct in external and intramedullary fixation systems involving plates and rods, with fracture braces and casting. Specifically, the Arthrex TightRope Acromioclavicular (AC) Device is intended to provide fixation during the healing process following a syndesmotic trauma, such as fixation of acromioclavicular separations due to	The Smith & Nephew Ultraslide Acromioclavicular and Syndesmotic Repair Device is intended as an adjunct in fracture repair providing fixation during the healing process following a syndesmotic trauma, such as fixation of acromioclavicular separations due to coracoclavicular ligament disruptions or fixation of ankle syndesmosis due to anterior inferior tibiofibular ligament and/or posterior inferior tibiofibular ligament disruptions.		The Surgicraft Surgical Mesh is intended for the reinforcement of the soft tissues which are repaired by suture or suture anchors during rotator cuff repair surgery. The mesh is not intended to replace normal body structure or provide full mechanical strength to support the rotator cuff. Sutures used to repair the tear, and sutures or bone anchor systems used to	

		coracoclavicular ligament disruptions.			attach the tissue to the bone, provide mechanical strength for tendon repair.	
Screws/ Washers	Screw diameter 3.5mm Lengths 14 – 40mm	Stainless Steel Buttons or Titanium Buttons (both Ti or SS), 3.5mm (oblong 3.5mm width and 10mm length) or 6.5mm (circular with 4 holes)	Titanium alloy ENDOBUTTONs 4mm x 12mm	Screw lengths 20 – 40mm		Screw diameter 0.8 – 3.5mm, Length – 2 – 40mm
Surgical Mesh	Identical to K072370	FiberWire UHMWPE blended with polyester, looped twice through the buttonholes.	Suture tape – polyester, poly(ethylene terephthalate) with a traction suture for placement		Identical	
Device Design						

In response to deficiency 4 of our July 10, 2009 request for additional information, the sponsor conducted additional testing using the Stryker Ø3.5mm cortical bone screw (Stryker AxSOS screw and plate system and extensions found in K092178, K061012, K060798, K060514 and K050512). The Ø3.5mm 10 to 150mm screws are referenced as compatible components on page 26 of K061012.

Reviewer Comment:

The 3.5mm diameter 20-40mm length screws have been previously cleared by Surgicraft in K080447. The sponsor is adding the lengths from 14-19mm to the system. The predicate and subject screws are composed of both Titanium and Stainless Steel. The identical mesh design was cleared in K072370.

(b)(4)



13

VI. Labeling

Instructions for Use

Amendment 4 includes the latest version of the "Instructions for Use". The "Instructions for Use" include the indications, contraindications, adverse effects, cautions, warnings, sterilization information and an overview of the surgical technique.

The sponsor added the following contraindication "**It is not intended that this technique be used as the sole means of reconstructing a chronic acromioclavicular joint dislocation.**" This contraindication is included in the Arthrex TightRope System Surgical Technique Guide (K052776).

The sponsor added the following warning in Amendment 4:

"The LockDown Acromioclavicular (AC) device has not been evaluated for safety and compatibility in the MR environment. The LockDown Acromioclavicular (AC) device has not been tested for heating or migration in the MR environment."

Reviewer Comment: *The Indications match the Indications for Use statement. The relevant contraindications and warnings are included and are similar to those included for the Arthrex Tightrope Acromioclavicular device (K052776). MR Compatibility has been addressed. There are no references to tissue in-growth of the LockDown device. The package insert is substantially equivalent to the labeling of the TightRope System.*

Surgical Technique Guide

The sponsor provided a revised Surgical Technique Guide in Amendment 2, dated February 10, 2011. The revised Surgical Technique Guide includes the indications, contraindications, directions for use with step-by-step figures, warnings, adverse effects and storage conditions.

The sponsor added the following contraindication "**It is not intended that this technique be used as the sole means of reconstructing a chronic acromioclavicular joint dislocation.**" This contraindication is included in the Arthrex TightRope System Surgical Technique Guide (K052776).

Reviewer Comment: *The US version of the surgical technique guide does not state the device is a ligament replacement. The sponsor indicates the UK surgical technique guide is not appropriate in the US. The surgical technique guide is adequate. The draft version of the surgical technique guide included the added contraindication in red with a red box around it. The sponsor stated in the final version of the surgical technique guide the text will be normal black font. The surgical technique guide shows the LockDown device being used in parallel between the AC ligaments, not replacing either one. This is adequate.*

Package Labels

Revised package labels are included in Attachment 5 of Supplement 1. The package labels include the device name, lot number, single use only, gamma irradiation, etc. The sponsor has incorporated statements for "Use by, Do not reuse and see instructions for use" in addition to the symbols. The sponsor name and contact information are on the end of the box.

Reviewer Comment: *The package labels are adequate.*

VII. Sterilization

(b)(4)



VIII. Biocompatibility

(b)(4)



(b)(4)



IX. Software – Not Applicable

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety – Not Applicable

XI. Performance Testing – Bench

(b) (4)



(b) (4)



(b) (4)



(b) (4)



(b) (4)



(b) (4)



21

(b) (4)



(b) (4)



(b) (4)



24

(b) (4)



(b) (4)



(b) (4)



(b) (4)



(b) (4)



References:

1. Costic RS, Labriola JE, Rodosky MW, Debski RE, Biomechanical rationale for development of anatomical reconstructions of coracoclavicular ligaments after complete acromioclavicular joint dislocations, Am J Sports Med, 2004, 32:1929.
2. Breslow MJ, Jazrawi LM et al. Treatment of Acromioclavicular joint separation: suture or suture anchors.
3. Nahum AM, Melvin JW, Accidental Injury 2nd edition, Springer-Verlag, New York, 2000.
4. Testing conducted and data provided by OrthoKinetic Testing Technologies, LLC – Shallotte, North Carolina.
5. Harris RI, Wallace AL, Harper GD, Goldberg JA, Sonnabend DH, Walsh WR, Structural properties of the intact and the reconstructed coracoclavicular ligament complex, The Am. Journal of Sports Medicine, Vol. 28, No. 1, 2000.

6. Motamedi AR, Blevins FT, Willis MC, McNally TP, Shahinpoor M, Biomechanics of the coracoclavicular ligament complex and augmentations used in its repair and reconstruction, The Am. Journal of Sports Medicine, Vo. 28, 2000, pp: 308.

7. Ma XY, Yin QS, Wu ZH, Xia H, Liu JF, Xiang M, Zhao WD, Zhong SZ. C1 pedicle screws versus C1 lateral mass screws: comparisons of pullout strengths and biomechanical stabilities. Spine. 2009 Feb 15;34(4):371-7.

8. Eck JC, Walker MP, Currier BL, Chen Q, Yaszemski MJ, An KN. Biomechanical comparison of unicortical versus bicortical C1 lateral mass screw fixation. J Spinal Disord Tech. 2007 Oct;20(7):505-8.

9. Cyr SJ, Currier BL, Eck JC, Foy A, Chen Q, Larson DR, Yaszemski MJ, An KN. Fixation strength of unicortical versus bicortical C1-C2 transarticular screws. Spine J. 2008 Jul-Aug;8(4):661-5. Epub 2007 May 11.

Reviewer Comments: *The sponsor has demonstrated equivalence in strength, stability, static and dynamic tensile strength, elongation and fixation between the Surgicraft LockDown AC Fixation System and the Arthrex TightRope AC Fixation System. Screw equivalence between the Surgicraft cortical fixation screw and the Stryker cortical bone screw was also demonstrated via the screw pullout assessment.*

XII. Performance Testing – Animal – Not Applicable

Animal Testing was not necessary to demonstrate the substantial equivalent of the LockDown AC Device.

XIII. Performance Testing – Clinical – Not Applicable

Clinical data were not necessary to demonstrate the substantial equivalent of the LockDown AC Device.

XIV. Substantial Equivalence Discussion

	Yes	No	
1. Same Indication Statement?	X		If YES = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NSE
3. Same Technological Characteristics?		X	If YES = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?	X		If YES = Go To 6
5. Descriptive Characteristics Precise Enough?			If NO = Go To 8 If YES = Stop SE
6. New Types Of Safety Or Effectiveness Questions?		X	If YES = Stop NSE
7. Accepted Scientific Methods Exist?	X		If NO = Stop NSE
8. Performance Data Available?	X		If NO = Request Data
9. Data Demonstrate Equivalence?	X		Final Decision: SE

Note: See

http://erom.fda.gov/eRoomReq/Files/CDRH3/CDRHPreMarketNotification510kProgram/0_4148/FLOWCART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please

complete the above table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:
2. Explain why there is or is not a new effect or safety or effectiveness issue:
3. **Describe the new technological characteristics:**
The predicate acromioclavicular devices use a suture and buttons for fixation. The subject device is a woven mesh that allows for tissue ingrowth and is fixed by screws.
4. **Explain how new characteristics could or could not affect safety or effectiveness:**
The mesh design will affect the performance of the device and will serve as a scaffold for tissue ingrowth affecting the safety and effectiveness.
5. Explain how descriptive characteristics are not precise enough:
6. **Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:**
The components of the device are all previously cleared. The questions being asked are similar to other acromioclavicular devices with regard to fixation and durability.
7. Explain why existing scientific methods can not be used:
8. Explain what performance data is needed:
9. **Explain how the performance data demonstrates that the device is or is not substantially equivalent:**
The sponsor has provided performance data evaluating screw fixation, static and dynamic tensile strength, elongation, strength of securing the device and possible failure modes. The LockDown device performed substantially equivalent to the Arthrex TightRope device.

(b) (4)



(b) (4)



K091207/S001

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-396-8118

(b) (4)



(b) (4)



(b) (4)



K091207/S001

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b) (4)



(b) (4)



XVI. Contact History

See CTS Interactive Review Summary.

XVII. Recommendation

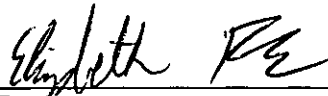
Based on the similarities in design, indications for use, material and characterization testing, the subject device is **Substantially Equivalent (SE)** to the Arthrex Tightrope (K052776). The sponsor has clearly included a contraindication that the device is "not intended to be used as the sole means of reconstructing a chronic acromioclavicular joint dislocation."

Regulation Number: 21 CFR 888.3030

Regulation Name: Single/Multiple component metallic bone fixation appliances and accessories

Regulatory Class: Class II

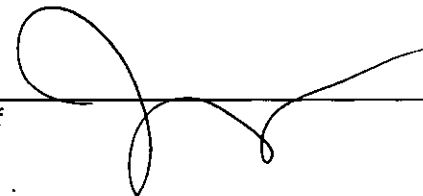
Product Code: HTN



Reviewer

2/14/11

Date



Branch Chief

2/15/2011

Date

Frank, Elizabeth L

From: McKinstry, Robert
Sent: Monday, March 22, 2010 9:36 AM
To: Foy, Jonette
Cc: Frank, Elizabeth L
Subject: RE: K091207/S1

(b)(4)



From: Foy, Jonette
Sent: Friday, March 19, 2010 8:14 AM
To: McKinstry, Robert
Cc: Frank, Elizabeth L
Subject: FW: K091207/S1
Importance: High

(b)(4)



Thanks,

Joni
Jonette Foy, Ph.D.
Chief, Orthopaedic Joint Devices Branch (OJDB)
Division of Surgical, Orthopaedic & Restorative Devices
FDA/CDRH/ODE
New Contact Info !!
WO66 Room #1508
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
Phone: 301-796-6910
Fax: 301-847-8119
Email Address: jonette.foy@fda.hhs.gov

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**K091207 Supplement 1
CTS Interactive Review Summary**

Date: 02/14/2011	Topic: Amendment 4 - MR Compatibility
Type: Email	User: Beth Frank
<p>Summary: From: Frank, Elizabeth L Sent: Monday, February 14, 2011 2:49 PM To: 'Don Guthner' Subject: RE: K091207 - Indications for Use Page</p> <p>No problem, thank you for your prompt response addressing the issue.</p> <p>Beth</p> <p>----- From: Don Guthner [mailto:dguthner@ptd.net] Sent: Monday, February 14, 2011 2:42 PM To: Frank, Elizabeth L Subject: RE: K091207 - Indications for Use Page</p> <p>Dear Beth, Attached is DRAFT copy of the revised IFU with the MR compatibility inserted. I apologize for the draft nature of the document.</p> <p>Regards,</p> <p>Don</p> <p>From: Frank, Elizabeth L Sent: Monday, February 14, 2011 11:02 AM To: 'Don Guthner' Subject: RE: K091207 - Indications for Use Page</p> <p>Dear Mr. Guthner, I did not see anything with regards to MR compatibility in the package insert. Please add the following warning to the package insert:</p> <p>"The LockDown Acromioclavicular (AC) device has not been evaluated for safety and compatibility in the MR environment. The LockDown Acromioclavicular (AC) device has not been tested for heating or migration in the MR environment."</p> <p>Thank you, best regards,</p> <p>Beth</p>	

Date: 02/14/2011	Topic: Amendment 3 - Indications for Use
Type: Email	User: Beth Frank
<p>Summary:</p> <p>From: Frank, Elizabeth L Sent: Monday, February 14, 2011 9:24 AM To: 'Don Guthner' Subject: RE: K091207 - Indications for Use Page</p> <p>Thank you, I received the attachment!</p> <p>-----</p> <p>From: Don Guthner [mailto:dguthner@ptd.net] Sent: Monday, February 14, 2011 9:19 AM To: Frank, Elizabeth L Subject: RE: K091207 - Indications for Use Page</p> <p>Dear Beth, Attached.</p> <p>Don</p> <p>From: Frank, Elizabeth L [mailto:Elizabeth.Frank@fda.hhs.gov] Sent: Monday, February 14, 2011 9:07 AM To: 'Don Guthner' Cc: 'Don Guthner'; Don Guthner Subject: K091207 - Indications for Use Page</p> <p>Hi Don,</p> <p>Do you think you could get me a revised indications for use page for the LockDown device? The indications for use page included in the submission has the original device name, not the modified LockDown device name. Please let me know if you could possibly get me that today. Thank you!</p> <p>Best regards,</p> <p>Beth</p>	

Date: 02/10/2011	Topic: Amendment 2
Type: Email	User: Beth Frank
<p>Summary:</p> <p>From: Frank, Elizabeth L Sent: Thursday, February 10, 2011 10:06 AM To: 'Don Guthner' Subject: RE: K091207 Response</p>	

Thank you Mr. Guthner. I received your emails will review everything this afternoon and let you know if I have any questions. You do not need to mail it to the document mail center, I will print the files and add them as an amendment to the file.

Beth

 From: Don Guthner [mailto:dguthner@hotmail.com]
 Sent: Thursday, February 10, 2011 10:03 AM
 To: Frank, Elizabeth L
 Subject: K091207 Response

Dear Dr. Frank,

I am sending you this response via email. I will follow up with triplicate hardcopy for delivery to FDA Document Center tomorrow.

I hope this response will enable you to complete your review. The Sponsor wanted me to tell you that the labeling is in draft condition due to the response time. The contraindication you requested to be added is in red type with a box around it. It will be in normal black type and font in the final document.

Regards,

Don

Date: 02/09/2011	Topic: Check on Response - Sponsor still working on it
Type: Email	User: Beth Frank
Summary:	
<p>From: Frank, Elizabeth L Sent: Wednesday, February 09, 2011 9:21 AM To: 'Don Guthner' Subject: RE: No Email</p> <p>Hi Don, Yes, if I can get a response from them early in the day tomorrow, I would try and finish the submission by AAOS. However, if I get it Friday or later I will likely not have a chance to finish it before I leave next week.</p> <p>Beth</p> <p>----- From: Don Guthner [mailto:dguthner@ptd.net] Sent: Wednesday, February 09, 2011 9:17 AM To: Frank, Elizabeth L Subject: RE: No Email</p> <p>Dear Beth,</p>	

I heard from the company today. They intend to have a response to me as quickly as possible, however, as you are aware, AAOS is next week and most companies are gearing up for that event. If I hear from them earlier, I will send it on to you.

Thank you for your patience.

Regards,

Don

From: Frank, Elizabeth L [mailto:Elizabeth.Frank@fda.hhs.gov]
Sent: Tuesday, February 08, 2011 11:58 AM
To: 'Don Guthner'
Subject: RE: No Email

Hi Don,

I just wanted to touch base with you and see how things are going. Please let me know when you anticipate submitting a response for review.

Thanks,

Beth

Date: 02/02/2011	Topic: No Email
Type: Email	User: Beth Frank
Summary: From: Don Guthner [mailto:dguthner@ptd.net] Sent: Wednesday, February 02, 2011 11:03 AM To: Frank, Elizabeth L Subject: RE: No Email Beth, I have sent emails on three accounts to Ryan McGowan (FDA). He helped resolve this issue last time. He responded to the email from this account. I am still in contact with the company, they are reviewing documents and will get back me quickly. They are anxious to complete the submission process for the product. Thank you. Regards, Don Guthner (personal email account) From: Frank, Elizabeth L [mailto:Elizabeth.Frank@fda.hhs.gov] Sent: Wednesday, February 02, 2011 11:00 AM To: Don Guthner	

Subject: No Email

Dear Mr. Guthner:

I wanted to let you know I have not received any emails from you.

Best regards,

Beth

Date: 02/01/2011	Topic: Check on Response
Type: Telephone Call	User: Beth Frank
Summary: Called sponsor to see if they had any questions, no response since sending request for AI. Sponsor has sent emails that sponsor is working on response, but emails blocked by FDA server. He will follow up with another email.	

Date: 01/27/2011	Topic: Request for Additional Information - Deficiency 1
Type: Email	User: Beth Frank
Summary: From: Frank, Elizabeth L Sent: Thursday, January 27, 2011 4:21 PM To: 'Don Guthner' Subject: Surgicraft LOCKDOWN AC Device Importance: High Dear Mr. Guthner: I would like to work with you to close out the Surgicraft LOCKDOWN AC 510(k) submission (K091207). I have the following deficiencies with the labeling and 510(k) Summary. Please take a look at these deficiencies and let me know if you will be able to address our concerns. I would be happy to discuss any concerns with you at your convenience	

(b) (4)



Date: 01/27/2011	Topic: Request for Additional Information - Deficiency 2
Type: Email	User: Beth Frank
Summary:	
(b) (4)	
<p>Thank you for your continued patience. I will let you know if there is any additional information I may need. Please let me know when you anticipate being able to respond. Best regards,</p> <p>Beth</p>	

Date: 04/06/2010	Topic: Sponsor called with status check
Type: Telephone Call	User: Beth Frank
Summary:	
<p>Informed sponsor file is still under review. Consultant asked to have this an email to forward to the sponsor.</p>	

Date: 04/06/2010	Topic: File Under Review
Type: Email	User: Beth Frank
Summary:	
<p>Sent: Tuesday, April 06, 2010 1:51 PM To: 'Don Guthner' Subject: K091207 Hi Don, As requested, I am notifying you to let you know the Surgicraft LOCKDOWN AC file is still under review and we have not yet made a determination of substantial equivalence. I will be in touch if I need any additional information. Best regards, Beth</p>	

Date: 01/14/2010	Topic: Table 8 Clarifications
Type: Email	User: Beth Frank
<p>Summary:</p> <p>From: Don Guthner [mailto:dg@orgenix.com] Sent: Thursday, January 14, 2010 3:41 PM To: Frank, Elizabeth L Subject: RE: K091207 Supplement 1 eCopy</p> <p>Dear Beth,</p> <p>The numbers in Table 8 of the original submission are still in the rev 2 testing report. They can be found in Tables 5a and 5b. These numbers show a comparison of the constructs. Please note that there is no significant difference in elongation between the constructs, even with a significant difference in tensile strength at failure.</p> <p>The numbers in the revised Table 8 are found in Table 6. After much discussion, it was felt that these 'Side-by-side' results were more appropriate to show substantial equivalence to a marketed predicate, as the elongation was measured at a physiologically relevant load (600N) that was greater than the threshold of the native human tissue failure.</p> <p>If you have any additional questions regarding the testing, Lisa Ferrara has suggested that you contact her directly (216) 401-3221.</p> <p>Thank you,</p> <p>Don.</p>	

Date: 01/14/2010	Topic: Request for Additional Clarification on Corrections 2
Type: Email	User: Beth Frank
<p>Summary:</p> <p>From: Frank, Elizabeth L Sent: Thursday, January 14, 2010 11:05 AM To: 'Don Guthner' Subject: RE: K091207 Supplement 1 eCopy</p> <p>Thank you Don. I see the differences between all of the pages you have updated (1-13, 1-27, 1-28 and 2-12 from Attachment 2).</p> <p>Could you please clarify why the numbers in attachment 2, table 8 have changed between the original submission and the latest amendment you submitted? I understand you indicated you included the wrong test report, but could you please explain the cause for the change. Thank you. - Beth</p>	

 From: Don Guthner [mailto:dg@orgenix.com]
 Sent: Thursday, January 14, 2010 10:57 AM
 To: Frank, Elizabeth L
 Subject: RE: K091207 Supplement 1 eCopy

Dear Beth,

Your first electronic copy already had the revised report in Attachment 2. Those pages will be the same between your two electronic copies. The differences between the two electronic copies I sent to you are:

Page Att. 1 & 13

Page Att. 1 & 27

Page Att. 1 & 28

Page Att. 1 & 13, we changed the 'smokestack' symbol to 'Manufactured by'
 Pages Att. 1 & 27 and 28 are the revised IFU.

Again, I apologize for the inconvenience.
 Don

Date: 01/14/2010	Topic: Request for Additional Clarification on Corrections
Type: Email	User: Beth Frank
Summary:	
<p>From: Frank, Elizabeth L Sent: Thursday, January 14, 2010 10:46 AM To: 'Don Guthner' Cc: Steve Trotman Subject: RE: K091207 Supplement 1 eCopy</p> <p>Don, Could you please list the items that are changed between the version you just sent me and the version logged in as Supplement 1. I am in the middle of reviewing your submission.</p> <p>Best regards, Beth</p>	

Date: 01/14/2010	Topic: Additional Corrections
Type: Email	User: Beth Frank
Summary:	
<p>From: Don Guthner [mailto:dg@orgenix.com] Sent: Thursday, January 14, 2010 8:35 AM To: Frank, Elizabeth L</p>	

Cc: Steve Trotman
 Subject: RE: K091207 Supplement 1 eCopy

Dear Beth,

I apologize for the inconvenience but we have discovered two more issues with the final submission. These are minor but I am sending in new pages in an 'Add-to-File' submission. I am sending you the (unsigned) letter with the table of the pages that will be changed ' for your reference only, as the letter is unsigned. I am also sending you another version (version 2) of the final electronic submission, with all corrections.

Again, I apologize for this inconvenience.

Regards,

Don

Date: 01/14/2010	Topic: Get back to you
Type: Email	User: Beth Frank
Summary:	
<p>From: Don Guthner [mailto:dg@orgenix.com] Sent: Thursday, January 14, 2010 11:15 AM To: Frank, Elizabeth L Subject: RE: K091207 Supplement 1 eCopy</p> <p>Dear Beth,</p> <p>I need to check with Lisa. I will get back to you as soon as I can.</p> <p>Thanks.</p> <p>Don</p>	

Date: 01/12/2010	Topic: eCopy Request
Type: Email	User: Beth Frank
Summary:	
<p>From: Frank, Elizabeth L Sent: Wednesday, January 13, 2010 10:24 AM To: 'Don Guthner' Subject: RE: K091207 Supplement 1 eCopy</p> <p>Thank you Don. I received the attachment.</p> <p>Beth</p>	

From: Don Guthner [mailto:dg@orgenix.com]
Sent: Tuesday, January 12, 2010 4:39 PM
To: Frank, Elizabeth L
Subject: RE: K091207 Supplement 1 eCopy

Dear Beth,

Attached is the submission with the correct report. The revised pages will be sent tomorrow to the Agency.

Regards,

Don

From: Frank, Elizabeth L [mailto:Elizabeth.Frank@fda.hhs.gov]
Sent: Tuesday, January 12, 2010 11:20 AM
To: Don Guthner
Subject: RE: K091207 Supplement 1 eCopy

Hi Don,

I am so sorry about the confusion. I just tried returning your call and got a voice mail recording. Please feel free to give me a call back. I apologize for getting names swapped between files. As for the incorrect test report, you may submit a new copy of the test report to the document mail center and it will be logged in as an amendment to the file. Please include a cover letter that states the test report is intended to replace the test report submitted in Supplement 1.

You can just send me an electronic copy of what needs to be reviewed, so it can be the appropriate test report. Please feel free to give me a call if you have any more questions. Thanks!

Beth

From: Frank, Elizabeth L
Sent: Monday, January 11, 2010 5:11 PM
To: 'dg@orgenix.com'
Subject: K091207 Supplement 1 eCopy

Hi David,

I am reviewing your response to our K091207 July 10, 2009 request for additional information for the LockDown AC Device. Would it be possible to email me an electronic copy of your response? Thank you so much.

Best regards,

Beth

Date: 01/12/2010	Topic: eCopy
Type: Telephone Call	User: Beth Frank
Summary: Sponsor submitted incorrect test report in Appendix 2. Sponsor will send a hard copy to the document mail center to be logged in as an amendment. Sponsor will send me an electronic copy of Supplement 1 that has the correct test report.	

Amendment 4

K091207/A4
2/14/11

Frank, Elizabeth L

From: Don Guthner [dguthner@ptd.net]
Sent: Monday, February 14, 2011 2:42 PM
To: Frank, Elizabeth L
Subject: RE: K091207 - Indications for Use Page
Attachments: 01a LockDown Acromioclavicular (AC) Device IFU-MR.PDF

Dear Beth,

Attached is DRAFT copy of the revised IFU with the MR compatibility inserted. I apologize for the draft nature of the document.

Regards,

Don

From: Frank, Elizabeth L [mailto:Elizabeth.Frank@fda.hhs.gov]
Sent: Monday, February 14, 2011 11:02 AM
To: 'Don Guthner'
Subject: RE: K091207 - Indications for Use Page

Dear Mr. Guthner,
I did not see anything with regards to MR compatibility in the package insert. Please add the following warning to the package insert:

"The LockDown Acromioclavicular (AC) device has not been evaluated for safety and compatibility in the MR environment. The LockDown Acromioclavicular (AC) device has not been tested for heating or migration in the MR environment."

Thank you, best regards,

Beth

From: Don Guthner [mailto:dguthner@ptd.net]
Sent: Monday, February 14, 2011 9:19 AM
To: Frank, Elizabeth L
Subject: RE: K091207 - Indications for Use Page

Dear Beth,

Attached.

Don

From: Frank, Elizabeth L [mailto:Elizabeth.Frank@fda.hhs.gov]
Sent: Monday, February 14, 2011 9:07 AM
To: 'Don Guthner'
Cc: 'Don Guthner'; Don Guthner

51

LockDown™ Acromioclavicular (AC) Device

Instructions for Use

INDICATIONS

The Surgicraft LockDown™ Acromioclavicular (AC) Device is intended to provide fixation during the healing process following a syndesmotic trauma, such as acromioclavicular separation, due to coracoclavicular ligament disruption.

CONTRAINDICATIONS

1. Insufficient quantity or quality of bone.
2. Blood supply limitations and previous infections, which may hinder healing.
3. Foreign-body sensitivity. Where material sensitivity is suspected, appropriate tests should be made and sensitivity ruled out prior to implantation.
4. Any active infection.
5. Conditions which tend to limit the patient's ability or willingness to restrict activities or follow directions during the healing period.
6. The use of this device may not be suitable for patients with insufficient or immature bone. The physician should carefully assess bone quality before performing orthopaedic surgery on patients who are skeletally immature. The use of this medical device and the placement of hardware or implants must not bridge, disturb, or disrupt the growth plate.
7. Do not use for surgeries other than those indicated.
8. It is not intended that this technique be used as the sole means of reconstructing a chronic acromioclavicular joint dislocation".

ADVERSE EFFECTS

1. Infections, both deep and superficial.
2. Allergies and other reactions to device materials.

CAUTION

Federal Law (U.S.A.) restricts LockDown™ Acromioclavicular (AC) Device to sale by or on the order of a physician. Only physicians qualified in appropriate surgical technique should use this device.

WARNINGS

1. All metal implants used for this surgical procedure must have the same metallurgical composition.
2. Postoperatively, until healing is complete the fixation provided by this device should be protected. The postoperative regimen prescribed by the physician should be strictly followed to avoid adverse stress to the implant.
3. Detailed instructions on the use and limitations of the device should be given to the patient.
4. Any decision to remove the device should take into consideration the potential risk to the patient of a second surgical procedure. Implant removal should be followed by adequate postoperative management.
5. Preoperative and operating procedures, including knowledge of surgical techniques and proper selection and placement of the implant, are important considerations in the successful utilisation of this device.
6. An internal fixation device must never be re-used.
7. Do not re-sterilise this device.
8. The appropriate Surgicraft instrumentation is required for proper insertion of the implant.

9. The LockDown Acromioclavicular (AC) device has not been evaluated for safety and compatibility in the MR environment. The LockDown Acromioclavicular (AC) device has not been tested for heating or migration in the MR environment."

9. Once open, discard any unused device.

PACKAGING AND LABELING

1. Surgicraft implants should be accepted only if the factory packaging and labelling arrive intact.
2. Contact Customer Service if package has been opened or altered.

STERILISATION

The LockDown™ Acromioclavicular (AC) Device has been sterilised with Gamma Irradiation. Provided that the integrity of the package is not compromised in any way, the package will serve as an effective barrier for 5 years from the date of sterilisation. There is a 5 year expiration date for product function or characteristics. This is a single use device and should not be re-sterilised. Surgicraft instruments, which should be used during this procedure, are provided non-sterile and must be adequately cleaned and sterilised prior to use or re-use.

MATERIAL SPECIFICATIONS

LockDown™ Acromioclavicular (AC) Device: Stainless Steel Screw and Washer to F138 or Titanium Alloy Screws and Washer to F136.

LockDown™ Mesh: Polyethyleneterephthalate, ie Polyester Fibres (PET)

STORAGE CONDITIONS

The LockDown™ Acromioclavicular (AC) Device must be stored in the original unopened packaging, away from moisture and should not be used after the expiration date.

INFORMATION

For more information, or a demonstration, contact your local Surgicraft representative.

DIRECTIONS FOR USE

Users of these devices are encouraged to contact their Surgicraft representatives if, in their professional judgment, they require a more comprehensive surgical technique.

LOCKDOWN™ ACROMIOCLAVICULAR (AC) DEVICE: Surgical Technique

1. The lateral end of the clavicle is exposed and the base of the coracoid identified via a shoulder strap incision.
2. 1cm of the lateral end of the clavicle is excised in the plane of the acromioclavicular joint.
3. The Tubular Introducer is passed around the base of the coracoid from medial to lateral, staying close to the bone.
4. The metal leader of the Length Gauge is passed through the Tubular Introducer from medial to lateral.
5. The Tubular Introducer is removed leaving the Length Gauge around the base of the coracoid.
6. The metal leader of the Length Gauge is passed through the loop at the other end of the Length Gauge removing any slack.
7. The metal leader of the Length Gauge is passed under the lateral end of the clavicle from anterior to posterior.

8. The clavicle is reduced to its anatomical position and the Length Gauge is held in the planned position of the LockDown™ Cortical Screw and Washer to measure the required LockDown™ Mesh length.

Note: The markings on the Length Gauge are 1cm apart. The double stitch represents an 11cm LockDown™ Mesh.

9. The metal leader is passed back under the clavicle and back through its loop to undo the anchorage point. The Length Gauge is NOT removed from under the coracoid.
10. The soft loop of the Length Gauge is passed through the hard loop of the chosen LockDown™ Mesh.
11. The soft loop of the Length Gauge is then passed over the soft loop of the LockDown™ Mesh.
12. The soft loop of the Length Gauge is then pulled down the length of the LockDown™ Mesh securing itself to the hard loop.
13. The LockDown™ Mesh is passed under the coracoid, by pulling the Length Gauge.
14. The metal leader of the Length Gauge is passed through the soft loop of the LockDown™ Mesh, positioning the LockDown™ Mesh around the base of the coracoid. Any slack is removed using the Loop Tensioner.
15. Using the metal leader as a guide, the Length Gauge is passed under the clavicle and the LockDown™ Mesh is tensioned across the superior aspect of the clavicle and the clavicle reduced.
16. The hard loop is anchored to the anterior clavicle using the LockDown™ Cortical Screw and Washer. The clavicle is prepared for the LockDown™ Cortical Screw and Washer using a drill and tap.

Note: The LockDown™ Cortical Screw and Washer should be inserted at an angle to avoid possible abrasion of the LockDown™ Mesh by the Screw tip.

17. Add an additional 4mm to the measured LockDown™ Cortical Screw length, to allow for the height of the washer and ensure bicortical fixation. The LockDown™ Cortical Screw and Washer are seated into place.

Note: Cut the Length Gauge from the hard loop of the LockDown™ Mesh before the LockDown™ Cortical Screw and Washer are fully seated.

18. All soft tissue is reconstructed over the top of the clavicle and acromioclavicular joint, and the wound closed in layers. The arm is supported for 2 weeks in a polysling and the patient is advised against heavy lifting for 3 months. Rehabilitation should progress at the surgeon's discretion.

SUGGESTED INSTRUCTIONS FOR USING LOCKDOWN™ ACROMIOCLAVICULAR (AC) DEVICE:

The recommend surgical technique above is designed to serve as a general guideline. It is not intended to supersede institutional protocols or professional clinical judgment concerning patient care.

Amendment 3

K091207/A3

2/14/11

Frank, Elizabeth L

From: Don Guthner [dguthner@ptd.net]
Sent: Monday, February 14, 2011 9:19 AM
To: Frank, Elizabeth L
Subject: RE: K091207 - Indications for Use Page
Attachments: K091207 Indications for Use.pdf

Dear Beth,

Attached.

Don

From: Frank, Elizabeth L [mailto:Elizabeth.Frank@fda.hhs.gov]
Sent: Monday, February 14, 2011 9:07 AM
To: 'Don Guthner'
Cc: 'Don Guthner'; Don Guthner
Subject: K091207 - Indications for Use Page

Hi Don,

Do you think you could get me a revised indications for use page for the LockDown device? The indications for use page included in the submission has the original device name, not the modified LockDown device name. Please let me know if you could possibly get me that today. Thank you!

Best regards,

Beth

Elizabeth L. Frank, M.S.
Biomedical Engineer
Orthopedic Joint Devices Branch
Division of Surgical, Orthopedic, and Restorative Devices
Phone: 301-796-6910
Fax: 301-847-8119
elizabeth.frank@fda.hhs.gov

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SURGICRAFT

Indications for Use

510(k) Number (if known): K091207

Device Name: **Surgicraft LOCKDOWN™ Acromioclavicular (AC) device**

The Surgicraft *LOCKDOWN™ Acromioclavicular (AC) device* is indicated to provide fixation during the healing process following a syndesmotic trauma, such as fixation of acromioclavicular separations due to coracoclavicular ligament disruptions.

Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Amendment 2K091207/A2
2/10/11**Frank, Elizabeth L**

From: Don Guthner [dguthner@hotmail.com]
Sent: Thursday, February 10, 2011 10:03 AM
To: Frank, Elizabeth L
Subject: K091207 Response
Attachments: 110209 K091207 AI response-r1.pdf; 110209 K091207 Attachment 1.pdf; 110209 K091207 Attachment 2.pdf

Dear Dr. Frank,

I am sending you this response via email. I will follow up with triplicate hardcopy for delivery to FDA Document Center tomorrow.

I hope this response will enable you to complete your review. The Sponsor wanted me to tell you that the labeling is in draft condition due to the response time. The contraindication you requested to be added is in red type with a box around it. It will be in normal black type and font in the final document.

Regards,

Don

Donald W. Guthner
Principal
Orgenix, LLC

www.orgenix.com
111 Hill Road
Douglassville, PA 19518
888-ORGENIX (674-3649)
646-460-2984 (Cell)
484-363-5879 (FAX)

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February 10, 2011

Office of Device Evaluation, 510(k)
Center of Devices and Radiological Health
Document Mail Center (WO66-0906)
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: K091207 – 510(k) Application – Surgicraft *LOCKDOWN*TM (AC) Device
Attn: Document Control Clerk
Reviewer: Elizabeth Frank

Dear Sir/Madam,

Orgenix, LLC is performing the role of consultant on behalf of:

Surgicraft (Trading name of Mandaco 569 Limited)

This letter and the Attachments comprise the Sponsor's response to the FDA email for Additional Information dated January 27, 2011. The Sponsor feels they have fully and completely responded in a constructive manner to all comments and requested labeling changes in the review of the 510(k) application K091207.

In this response FDA's original comments are reproduced in italics. The response to each section follows. Any documents referenced can be found in the corresponding Appendix, unless noted (to reduce duplication). For example, the documents referred to in Question 1 can be found in Appendix 1, those referred to in Question 2 in Appendix 2 and so on.

(b) (4)



111 Hill Road * Douglassville, PA 19518
(646) 460-2984 * (888) ORGENIX * (484) 363-5879 (FAX)
www.orgenix.com

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(b) (4)

A revised 510(k) summary is included in Attachment 2. All of the requested changes have been included in the revised summary.

It has been the intention of the Sponsor to completely respond to the questions raised in this letter. If you have any questions regarding any of the responses, please do not hesitate to ask.

Regards,



Donald W. Guthner
Principal



2011 59

ATTACHMENT 1

Records processed under FOIA Request # 2015-684; Released by CDRH on 10-08-2015

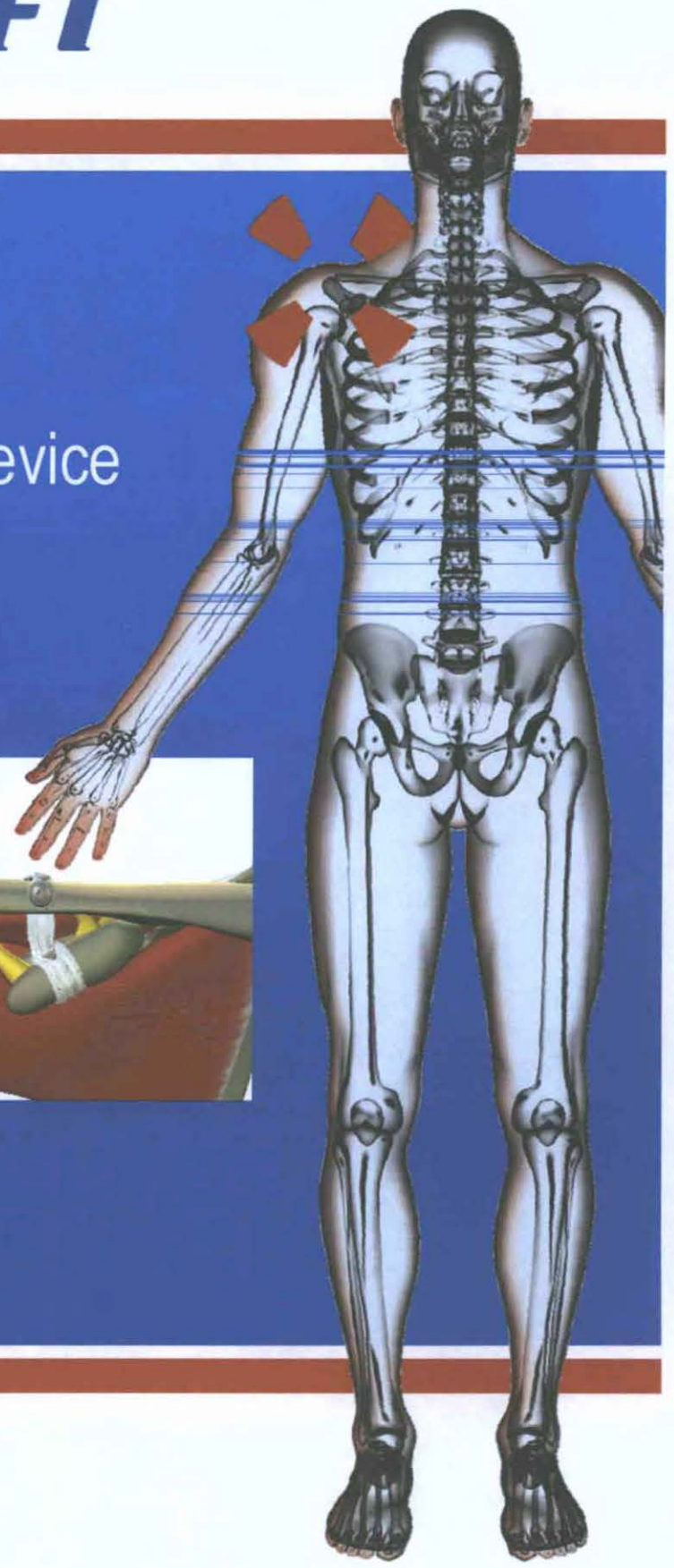
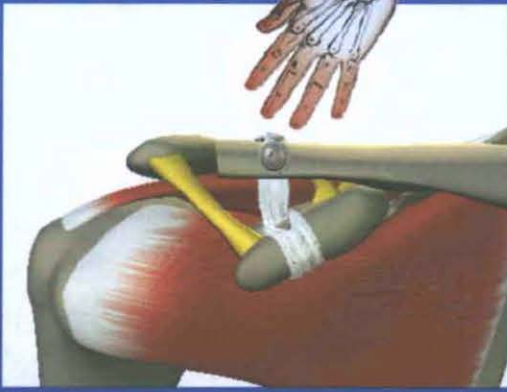
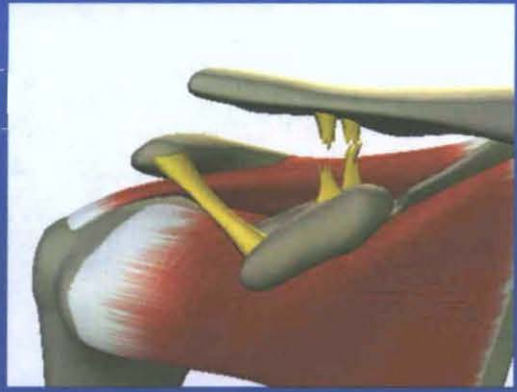
Records processed under FOIA Request # 2015-684; Released by CDRH on 10-08-2015

Records processed under FOIA Request # 2015-684; Released by CDRH on 10-08-2015

Final

SURGICRAFT

LockDown™ Acromioclavicular (AC) Device



Product Information

Instructions For Use

INDICATIONS

The LockDown™ Acromioclavicular (AC) Device is intended to provide fixation during the healing process following a syndesmotic trauma, such as acromioclavicular separation, due to coracoclavicular ligament disruption.

CONTRAINDICATIONS

1. Insufficient quantity or quality of bone.
2. Blood supply limitations and previous infections, which may tend to retard healing.
3. Foreign-body sensitivity. Where material sensitivity is suspected, appropriate tests should be made and sensitivity ruled out prior to implantation.
4. Any active infection.
5. Conditions which tend to limit the patient's ability or willingness to restrict activities or follow directions during the healing period.
6. The use of this device may not be suitable for patients with insufficient or immature bone. The physician should carefully assess bone quality before performing orthopaedic surgery on patients who are skeletally immature. The use of this medical device and the placement of hardware or implants must not bridge, disturb, or disrupt the growth plate.
7. Do not use for surgeries other than those indicated.

8. It is not intended that this technique be used as the sole means of reconstructing a chronic acromioclavicular joint dislocation.

BACKGROUND

Disruption of the coracoclavicular ligaments is a common occurrence. In many cases the injury can be treated conservatively and the only residual problem is that of a mild cosmetic deformity.

Several groups of patients, however, do not tolerate the injury well. These include the very thin, the very large and the overhead athlete. If the joint is reduced acutely and held and reduced during the healing phase, the native ligaments will heal restoring the stability of the joint.

This technique provides a simple and reproducible surgical technique for acromioclavicular joint stabilisation which enables a rapid return to activity injury.

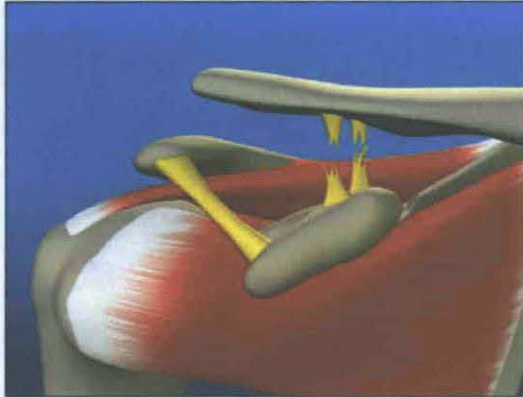
Developed in conjunction with Prof. W. A. Wallace, FRCS, Nottingham, England.

DIRECTIONS FOR USE

Users of this device are encouraged to contact their Surgicraft representative if, in their professional judgment, they require a more comprehensive surgical technique.

LockDown™ AC Device SURGICRAFT

Surgical Technique

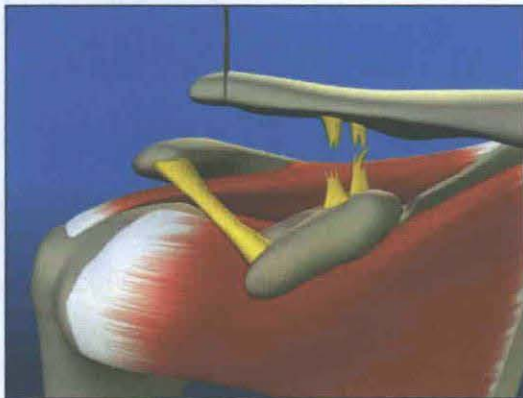


Preparation

The patient is positioned in a deck chair position, and routine surgical preparation of the skin is performed.

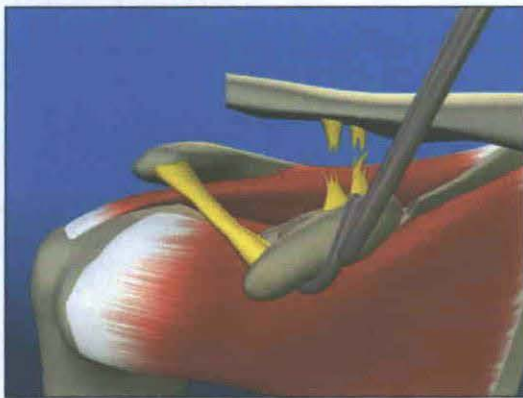
Step 1

The lateral end of the clavicle is exposed and the base of the coracoid identified via a shoulder strap incision.



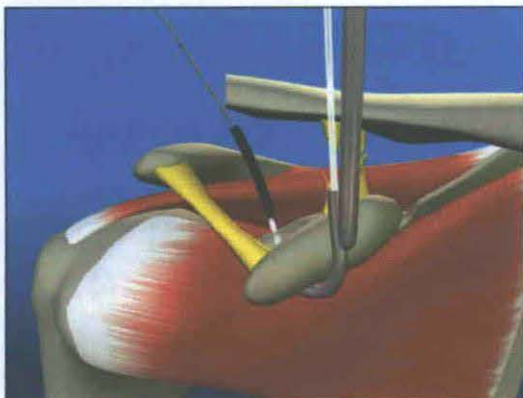
Step 2

1cm of the lateral end of the clavicle may be excised in the plane of the acromioclavicular joint, especially in chronic cases, to avoid any post operative impingement.



Step 3

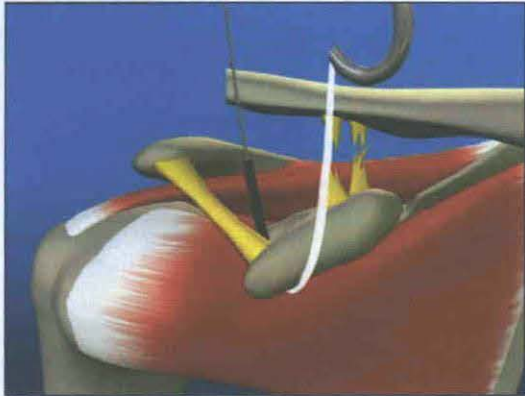
The Tubular Introducer is passed around the base of the coracoid from medial to lateral, staying close to the bone.



Step 4

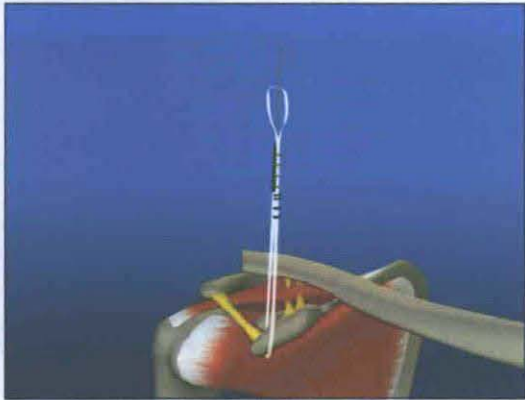
The metal leader of the Length Gauge is passed through the Tubular Introducer from medial to lateral.

Surgical Technique



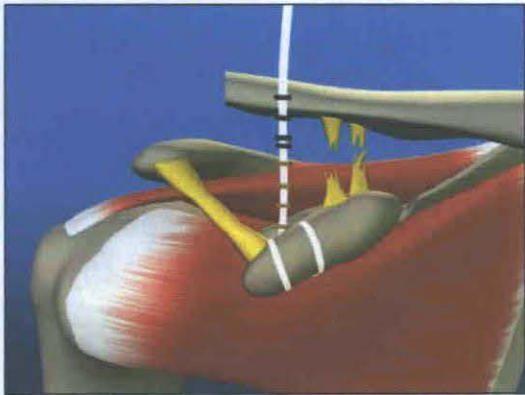
Step 5

The Tubular Introducer is removed leaving the Length Gauge around the base of the coracoid.



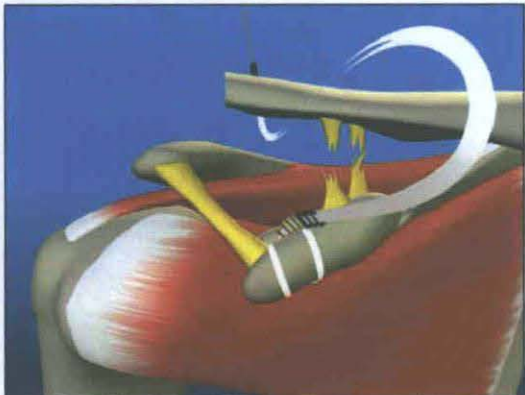
Step 6

The metal leader of the Length Gauge is passed through the loop at the other end of the Length Gauge.



Step 7

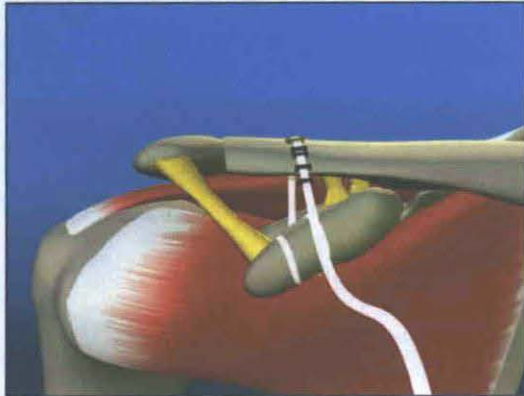
The Length Gauge is tightened around the coracoid removing any slack.



Step 8

The metal leader of the Length Gauge is passed under the lateral end of the clavicle from anterior to posterior.

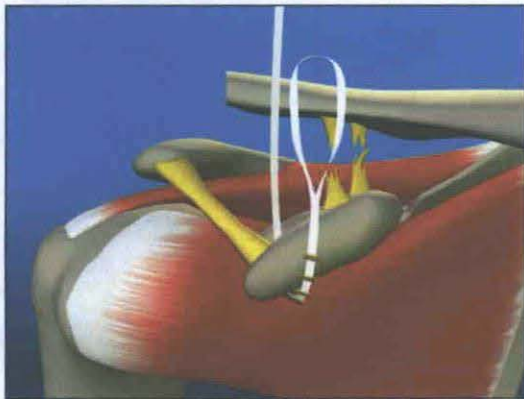
Surgical Technique



Step 9

The clavicle is reduced to its anatomical position and the Length Gauge is held in the planned position of the LockDown™ Screw and Washer to measure the required LockDown™ AC Device length.

Note: The markings on the Length Gauge are 1cm apart. The double stitch represents an 11cm LockDown™ AC Device.



Step 10

The metal leader is passed back under the clavicle and back through its loop to undo the anchorage point. The Length Gauge is NOT removed from under the coracoid.



Step 11

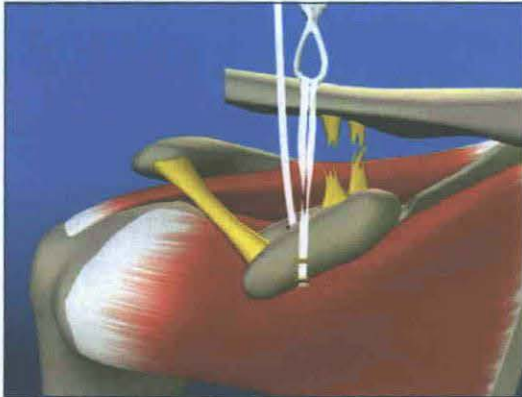
The soft loop of the Length Gauge is passed through the hard loop of the chosen LockDown™ AC Device.



Step 12

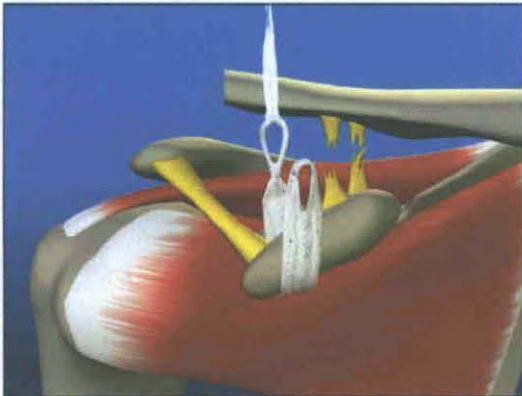
The soft loop of the Length Gauge is then passed over the soft loop of the LockDown™ AC Device.

Surgical Technique



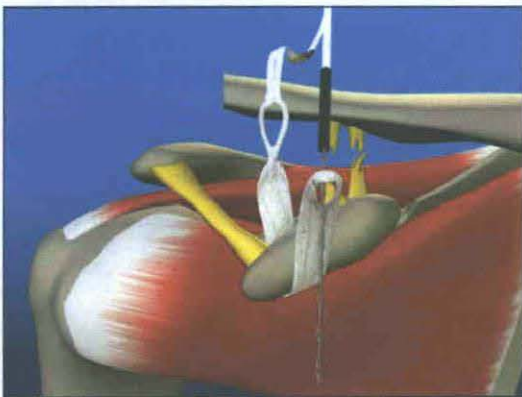
Step 13

The soft loop of the Length Gauge is then pulled down the length of the LockDown™ AC Device securing itself to the hard loop.



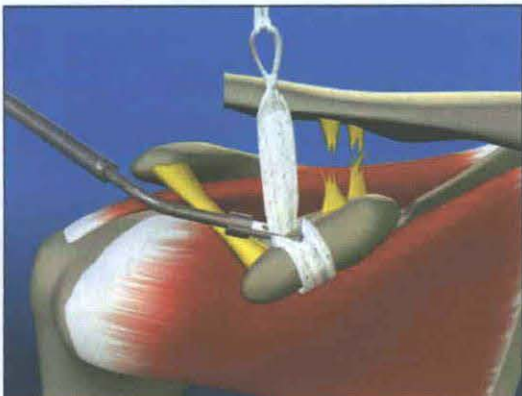
Step 14

The LockDown™ AC Device is passed under the coracoid, by pulling the Length Gauge.



Step 15

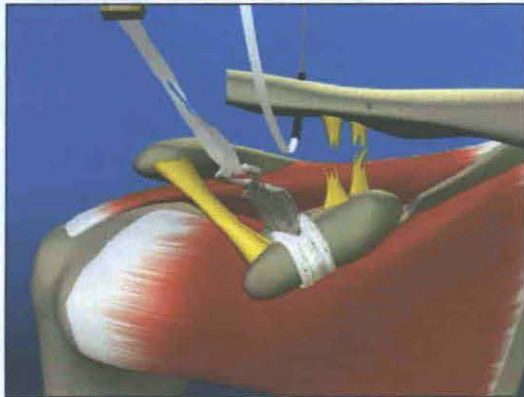
The metal leader of the Length Gauge is passed through the soft loop of the LockDown™ AC Device. This in turn leads the hard loop of the LockDown™ AC Device through the soft loop of the LockDown™ AC Device.



Step 16

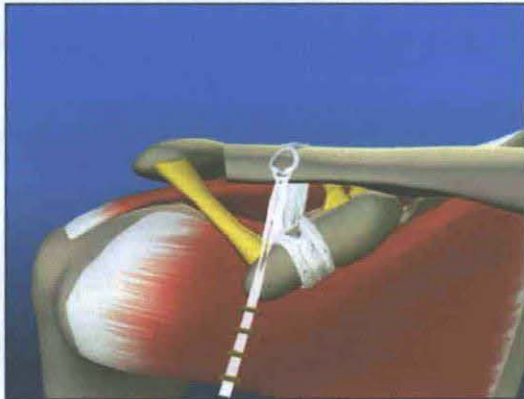
The soft loop of the LockDown™ AC Device is positioned around the base of the coracoid. Any slack is removed using the Loop Tensioner.

Surgical Technique



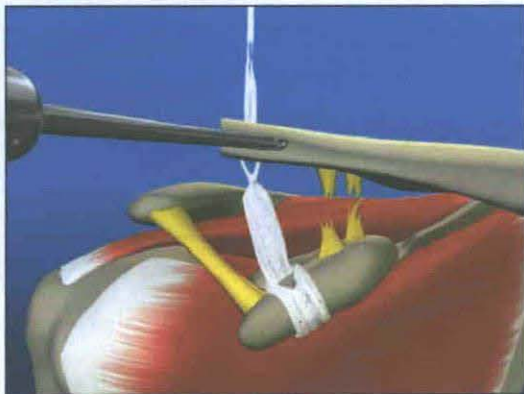
Step 17

Using the metal leader as a guide, the Length Gauge is passed under the clavicle.



Step 18

The LockDown™ AC Device is tensioned across the superior aspect of the clavicle and the clavicle reduced.



Step 19

The hard loop is anchored to the anterior clavicle using the LockDown™ Screw and Washer. The clavicle is prepared for the LockDown™ Screw and Washer using a drill and tap.

Note: Ensure that the LockDown™ AC Device is clear of the drill during the screw preparation step so as not to damage the LockDown™ AC Device material.

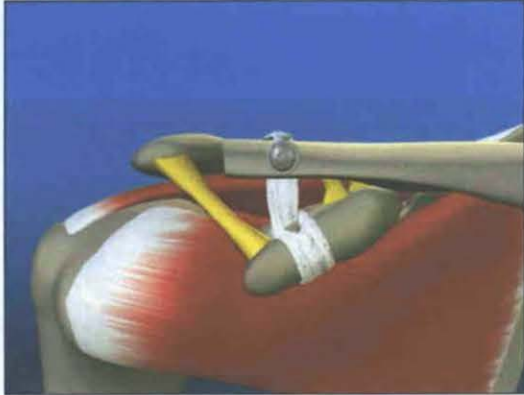


Step 20

The LockDown™ Screw and Washer should be inserted at an angle to avoid possible abrasion of the LockDown™ AC Device by the Screw tip.

Add an additional 4mm to the measured LockDown™ Screw length, to allow for the height of the washer and ensure bicortical fixation.

Surgical Technique



Step 21

The LockDown™ Screw and Washer are seated into place.

Note: Cut the Length Gauge from the hard loop of the LockDown™ AC Device before the LockDown™ Screw and Washer are fully seated.



Step 22

All soft tissue is reconstructed over the top of the clavicle and acromioclavicular joint, and the wound closed in layers. The arm is supported for 2 weeks in a polysling and the patient is advised against heavy lifting for 3 months. Rehabilitation should progress at the surgeon's discretion.

SUGGESTED INSTRUCTIONS FOR USING LOCKDOWN™ ACROMIOCLAVICULAR (AC) DEVICE:

The recommended surgical technique above is designed to serve as a general guideline. It is not intended to supersede institutional protocols or professional clinical judgment concerning patient care.

Warnings and Precautions

WARNINGS

1. All metal implants used for this surgical procedure must have the same metallurgical composition.
2. Postoperatively, until healing is complete, the fixation provided by this device should be protected. The postoperative regimen prescribed by the physician should be strictly followed to avoid adverse stress to the implant.
3. Detailed instructions on the use and limitations of the device should be given to the patient.
4. Any decision to remove the device should take into consideration the potential risk to the patient of a second surgical procedure. Implant removal should be followed by adequate postoperative management.
5. Preoperative and operating procedures, including knowledge of surgical techniques and proper selection and placement of the implant, are important considerations in the successful utilisation of this device.
6. An internal fixation device must never be reused.
7. Do not re-sterilise this device.
8. The appropriate Surgicraft instrumentation is required for proper insertion of the implant.
9. Once open, discard any unused device.

ADVERSE EFFECTS

1. Infections, both deep and superficial.
2. Allergies and other reactions to device materials.

PACKAGING AND LABELING

1. Surgicraft implants should be accepted only if the factory packaging and labelling arrive intact.
2. Contact Customer Service if package has been opened or altered.

STERILISATION

The device is supplied sterile. Refer to the package label for the sterilisation method. Certain Surgicraft instruments that may be used during this procedure are provided non-sterile and must be adequately cleaned and sterilised prior to use or re-use. Please refer to DFU-0023 and ANSI/AAMI ST46, "Good Hospital Practice: Steam Sterilisation and Sterility Assurance," for specific information.

MATERIAL SPECIFICATIONS

LockDown™ Acromioclavicular (AC) Device: Stainless Steel Screw and Washer to F138 or Titanium Alloy Screws and Washer to F136.

LockDown™ AC Device: Polyethyleneterephthalate, i.e. Polyester Fibres (PET)

STORAGE CONDITIONS

The LockDown™ Acromioclavicular (AC) Device must be stored in the original unopened packaging, away from moisture and should not be used after the expiration date.

INFORMATION

For more information, or a demonstration, contact your local Surgicraft representative.

CAUTION

The LockDown™ Acromioclavicular (AC) Device has not been evaluated for safety and compatibility in the MR environment. The LockDown™ Acromioclavicular (AC) Device has not been tested for heating or migration in the MR environment.

Federal Law (U.S.A.) restricts LockDown™ Acromioclavicular (AC) Device to sale by or on the order of a physician. Only physicians qualified in appropriate surgical technique should use this device.

SURGICRAFT

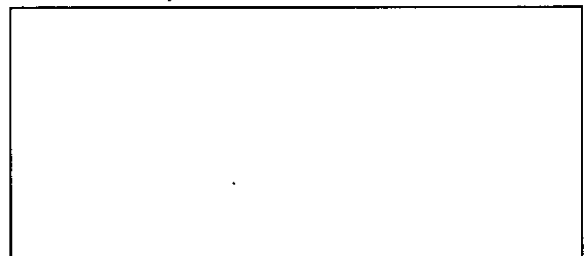
LockDown™ Acromioclavicular (AC) Device

CODE	DESCRIPTION
LD050	LockDown™ 5cm Acromioclavicular (AC) Device*
LD060	LockDown™ 6cm Acromioclavicular (AC) Device*
LD070	LockDown™ 7cm Acromioclavicular (AC) Device
LD080	LockDown™ 8cm Acromioclavicular (AC) Device
LD090	LockDown™ 9cm Acromioclavicular (AC) Device
LD100	LockDown™ 10cm Acromioclavicular (AC) Device
LD110	LockDown™ 11cm Acromioclavicular (AC) Device
LD120	LockDown™ 12cm Acromioclavicular (AC) Device
LD130	LockDown™ 13cm Acromioclavicular (AC) Device
LD140	LockDown™ 14cm Acromioclavicular (AC) Device*
LD150	LockDown™ 15cm Acromioclavicular (AC) Device*
LD160	LockDown™ 16cm Acromioclavicular (AC) Device*
LD170	LockDown™ 17cm Acromioclavicular (AC) Device*
LD180	LockDown™ 18cm Acromioclavicular (AC) Device*
LD190	LockDown™ 19cm Acromioclavicular (AC) Device*
LD200	LockDown™ 20cm Acromioclavicular (AC) Device*
LDLG	LockDown™ Length Gauge
LDSS14	14mm Cortical Screw (3.5mm Dia) & 1mm Washer (SS)
LDSS16	16mm Cortical Screw (3.5mm Dia) & 1mm Washer (SS)
LDSS18	18mm Cortical Screw (3.5mm Dia) & 1mm Washer (SS)
LDSS20	20mm Cortical Screw (3.5mm Dia) & 1mm Washer (SS)
LDSS22	22mm Cortical Screw (3.5mm Dia) & 1mm Washer (SS)
LDSS24	24mm Cortical Screw (3.5mm Dia) & 1mm Washer (SS)
LDSS26	26mm Cortical Screw (3.5mm Dia) & 1mm Washer (SS)
LDSS28	28mm Cortical Screw (3.5mm Dia) & 1mm Washer (SS)
LDSS30	30mm Cortical Screw (3.5mm Dia) & 1mm Washer (SS)
LDSS32	32mm Cortical Screw (3.5mm Dia) & 1mm Washer (SS)
LDSS34	34mm Cortical Screw (3.5mm Dia) & 1mm Washer (SS)
LDSS36	36mm Cortical Screw (3.5mm Dia) & 1mm Washer (SS)
LDSS38	38mm Cortical Screw (3.5mm Dia) & 1mm Washer (SS)
LDSS40	40mm Cortical Screw (3.5mm Dia) & 1mm Washer (SS)


* Special sizes available on request only.

Surgicraft
 (Trading Name of Mandaco 569 Limited)
 16 The Oaks
 Clews Road
 Redditch
 Worcestershire
 B98 7ST
 ENGLAND

Distributed by:



Tel: +44(0)1527 555888
 Fax: +44(0)1527 551166
 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8448
 customerservice@surgicraft.co.uk
 www.surgicraft.co.uk

 Surgicraft (Trading Name of Mandaco 569 Limited)
 16 The Oaks, Clews Road, Redditch, UK, B98 7ST
 www.surgicraft.co.uk



ATTACHMENT 2



510(k) Summary

Contact: Donald W. Guthner
Orgenix, LLC
111 Hill Road
Douglassville, PA 19518
(646) 460-2984

Device Trade Name: *LOCKDOWN™ Acromioclavicular (AC) device.*

Manufacturer: Surgicraft (Trading Name of Mandaco 569 Limited)
16 The Oaks
Clews Road
Redditch, UK
B98 7ST

Classification: 21 CFR 888.3030, Single/multiple component metallic bone fixation appliances and accessories

Class: II

Product Code: HTN

Indications For Use:

The Surgicraft *LOCKDOWN™ Acromioclavicular (AC) device* is indicated to provide fixation during the healing process following a syndesmotric trauma, such as fixation of acromioclavicular separations due to coracoclavicular ligament disruptions.

Device Description:

The Surgicraft *LOCKDOWN™ Acromioclavicular (AC) device* is a combination of two FDA-cleared Surgicraft Products, the Surgicraft LOCKDOWN Mesh (K072370) and the Surgicraft LOCKDOWN Screw (K080447). The new product for this indication is designated as the *LOCKDOWN™ Acromioclavicular (AC) device* and will have a new indication to provide fixation during the healing process following a syndesmotric trauma, such as fixation of acromioclavicular separations due to coracoclavicular ligament disruptions.

It is not intended that the Surgicraft *LOCKDOWN™ Acromioclavicular (AC) device* be used as the sole means of reconstructing a chronic acromioclavicular joint dislocation.

The *Surgicraft LOCKDOWN Mesh* device is a woven mesh 11mm wide by 4 to 20 cm in length with loops at both ends. The Surgical Mesh is made from braided Polyethyleneterephthalate (Polyester) fibers (PET).

Manufactured by:
Surgicraft (Trading name of Mandaco 569) / 16 The Oaks / Clews Road / Redditch / Worcestershire / B98 7ST / UK
T: +44 1527 512600 / F: +44 1527 512612 / E: info@surgicraft.co.uk / www.surgicraft.co.uk

The *Surgicraft LOCKDOWN Screw* is manufactured from stainless steel and titanium alloy. The self-tapping 3.5 mm screws are available in lengths from 14- 40 mm in 1 mm increments. The washers have a hole with an inner diameter of 4.2 mm and an outer diameter ranging from 7 to 9 mm in 1 mm increments.

The Surgicraft *LOCKDOWN™ Acromioclavicular (AC) device* is provided sterile.

Predicate Device(s):

The Surgicraft *LOCKDOWN™ Acromioclavicular (AC) device* was shown to be substantially equivalent to the Arthrex TightRope® Acromioclavicular device (K052776) and has the same indications for use, function and/or materials.

- The Surgicraft *LOCKDOWN™ Acromioclavicular (AC) device* and the named predicate device both use braided Polyethyleneterephthalate (Polyester) fibers (PET), stainless steel and titanium materials to fixate acromioclavicular separations.
- Both devices contraindicate the use of the device as the sole means of reconstructing a chronic acromioclavicular joint dislocation.
- The indications for use statements for both devices are identical.

Performance Standards:

No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act applicable to this device. Side-by-side testing was performed with the named predicate device in appropriate cadaver models and indicated that the Surgicraft *LOCKDOWN™ Acromioclavicular (AC) device* is substantially equivalent to predicate device.

Non-Clinical Testing

Mechanical testing was performed on the Surgicraft *LOCKDOWN™ Acromioclavicular (AC) device* or its components prior to submission for approval. Testing performed included biocompatibility testing (per ISO 10993), screw pull-out testing, mesh burst strength and suture attachment strength. In addition, side-by-side testing was performed against the predicate device in an appropriate cadaveric model.

Clinical Testing

No clinical testing was performed nor was deemed necessary to demonstrate substantial equivalence.

Conclusions

Surgicraft considers the *LOCKDOWN™ Acromioclavicular (AC) device* to be equivalent to the predicate device listed above. This conclusion is based upon the devices similarities in function, materials and indications for use.



COVER SHEET MEMORANDUM

From: Reviewer Name Elizabeth Frank
Subject: 510(k) Number K091207
To: The Record

Please list CTS decision code AI

- Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)
- Hold (Additional Information or Telephone Hold).
- Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU		
510(k) Summary /510(k) Statement	Attach Summary		
Truthful and Accurate Statement.	Must be present for a Final Decision		
Is the device Class III?			
If yes, does firm include Class III Summary?	Must be present for a Final Decision		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, <i>Certification with Requirements of ClinicalTrials.gov Data Bank</i> ? (If not, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			
All Pediatric Patients age <= 21			
Neonate/Newborn (Birth to 28 days)			
Infant (29 days - < 2 years old)			
Child (2 years - < 12 years old)			
Adolescent (12 years - < 18 years old)			
Transitional Adolescent A (18 - < 21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			
Transitional Adolescent B (18 - <= 21; No special considerations compared to adults => 21 years old)			
Nanotechnology			

Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	Contact OSB.		
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	Contact OC.		

Regulation Number **Class*** **Product Code**

(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review:

(Branch Chief)

(Branch Code)

(Date)

Final Review:

(Division Director)

(Date)



DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

**Premarket Notification [510(k)] Review
Traditional**

K091207

Date: July 10, 2009

To: The Record

From: Elizabeth Frank, MS, Biomedical Engineer

Office: ODE

Division: DSORD/OJDB

510(k) Holder: Surgicraft, Ltd.

Device Name: Surgicraft SURGILIG™ Acromioclavicular (AC) Device)

Contact: Mr. Donald W. Guthner

Orgenix, LLC

111 Hill Road

Douglassville, PA 19518

Phone: 646-460-2984

Fax: 484-363-5879

Email: dq@orgenix.com

I. Purpose and Submission Summary

The 510(k) holder would like to introduce the Surgicraft SURGILIG™ Acromioclavicular (AC) Device into interstate commerce. The Surgicraft™ SURGILIG™ Acromioclavicular (AC) device is a combination of two FDA-cleared Surgicraft Products, the Surgicraft Surgical Mesh (K072370) and the Surgicraft Screw Fixation System (K080447). The new SURGILIG™ Acromioclavicular (AC) device will have a new indication to provide fixation during the healing process following a syndesmotic trauma, such as fixation of acromioclavicular separations due to coracoclavicular ligament disruptions. The Surgicraft Surgical Mesh device is a woven mesh 11mm wide by 4 to 20 cm in length with loops at both ends. The Surgical Mesh is made from Polyethyleneterephthalate (i.e. Polyester fibers (PET)). The Surgicraft Screw Fixation System is manufactured from stainless steel 316L and titanium alloy 6Al4V ELI. The self-tapping 3.5mm screws are available in lengths from 14-40mm in 1mm increments. The washers have a hole with an inner diameter of 3.9mm and an outer diameter ranging from 7 to 9mm in 1mm increments.

The sponsor did not include a complete surgical technique guide with the submission, only an overview of steps in the Instructions for Use. There is a surgical technique guide for the device available on the sponsor's United Kingdom website. The surgical technique guide is for the "Surgilig® Acromio-Clavicular Ligament" and is described as "a synthetic ligament used in acromion-clavicular reconstruction to replace the ligament and recreate the anatomy. It is made of double braided polyester with a patented weave design which acts as a scaffold encouraging tissue in-growth (predominantly scar tissue)." Based on this description it appears the subject device is a ligament replacement. There are also numerous references in the test reports to ligaments.

The sponsor provided comprehensive characterization data on the screw and mesh. The 14mm and 20mm screws were evaluated for pullout resistance and torsional strength. The mesh was evaluated for static and dynamic tensile stresses, burst strength, and suture pullout strength. The sponsor has

adequately characterized the screws and mesh, however, the sponsor has not evaluated the construct as a whole in comparison to a legally marketed predicate device.

The sponsor will be sent a letter requesting **Additional Information (AI)** to address the deficiencies at the conclusion of the memo. The main deficiency outlines the information the sponsor has submitted supporting that the subject device is actually a ligament replacement which is considered a post amendments Class III device and requires PMA approval.

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	X		
Truthful and Accuracy Statement	X		
510(k) Summary or 510(k) Statement	X		
Standards Data Report for 510(k)s (Form 3654)	X		
Clinical Trials Form (Form 3674)	X		

The Standards Forms and Clinical Trials Form are included in Attachment 1

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?	X		
Does the device design use software?		X	
Is the device sterile?	X		
Is the device reusable (not reprocessed single use)?		X	
Are "cleaning" instructions included for the end user?		X	

(b)(4)



Figure 1: Surgical Mesh Desgin

(b)(4)



IV. Indications for Use

The Surgicraft *SURGILIG™ Acromioclavicular (AC) device* is indicated to provide fixation during the healing process following a syndesmotic trauma, such as fixation of acromioclavicular separations due to coracoclavicular ligament disruptions.

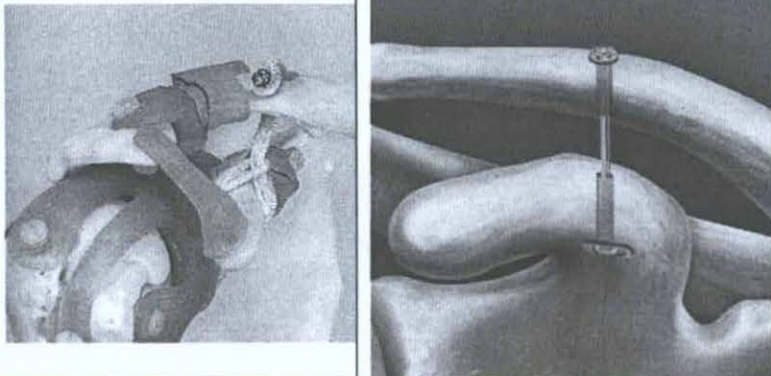
Reviewer Comment: The indications for use are identical to the indications for the TightRope™ Acromioclavicular (AC) device (K052776) and the Smith & Nephew Ultraslide Acromioclavicular and Syndesmotic Repair Device (K082095).

V. Predicate Device Comparison

The sponsor provides a predicate device comparison in Table 4.

Table 4: Predicate Device Comparison

Manufacturer	Surgicraft	Arthrex	Surgicraft	Surgicraft	Howmedica-Leibinger
Device Name	SURGILIG™ Acromioclavicular (AC) device	TightRope™ Acromioclavicular (AC) device	Screw Fixation System	Surgical Mesh	Luhr® Small Orthopedic Bone Screw System
510(k) Number	Subject	K052776	K080447	K072370	K963679
Product Code	HTN	HTN	HWC	FTL	HWC
Materials	Titanium Alloy Stainless Steel Polyester (PET) fiber	Titanium Alloy UHMWPE Polyester	Titanium Alloy Stainless Steel	Polyester (PET) fiber	Titanium Alloy
Indications for Use	The Surgicraft <i>SURGILIG™ Acromioclavicular (AC) device</i> is indicated to provide fixation during the healing process following a syndesmotic trauma, such as fixation of acromioclavicular separations due to coracoclavicular ligament disruptions.	The TightRope™ Acromioclavicular (AC) Device is intended as an adjunct in fracture repair involving metaphyseal and periarticular small bone fragments where screws are not indicated, and as an adjunct in external and intramedullary fixation systems involving plates and rods, with fracture braces and casting. Specifically, the Arthrex TightRope Acromioclavicular (AC) Device is intended to provide fixation during the healing process following a syndesmotic trauma, such as fixation of acromioclavicular separations due to coracoclavicular ligament disruptions.		The Surgicraft Surgical Mesh is intended for the reinforcement of the soft tissues which are repaired by suture or suture anchors during rotator cuff repair surgery. The mesh is not intended to replace normal body structure or provide full mechanical strength to support the rotator cuff. Sutures used to repair the tear, and sutures or bone anchor systems used to attach the tissue to the bone, provide mechanical strength for tendon repair.	

Screws/ Washers	Screw diameter 3.5mm Lengths 14 – 40mm		Screw lengths 20 – 40mm		Screw diameter 0.8 – 3.5mm, Length – 2 – 40mm
Surgical Mesh	Identical			Identical	
Device Design					

(b)(4)

In their comparison to predicate devices the sponsor does not include the Smith & Nephew Ultraslide Acromioclavicular and Syndesmotic Repair Device (K082095). The Ultraslide consists of two ENDOBUTTON devices and a suture tape composed of polyester. The device is threaded through a pre-drilled bone tunnel and the ENDOBUTTON is placed appropriately. The surgeon is then able to pull on the suture tape to reduce the Acromioclavicular separation to tighten down the trailing button. When the reduction position is confirmed via visualization, a surgical knot will be made over the top of the Ultraslide device. A good photograph of the Ultraslide was not included in the original submission (K082095), making it difficult to compare to the subject device. However, it does appear to be more of a "meshlike" design than the Arthrex tigtrope suture. The

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sponsor will be asked to provide a better predicate comparison to demonstrate substantial equivalence, so they will likely include this predicate device in their comparison.

The 3.5mm diameter 20-40mm length screws have been previously cleared by Surgicraft in K080447. The sponsor is adding the lengths from 14-19mm to the system. The predicate and subject screws are composed of both Titanium and Stainless Steel. The identical mesh design was cleared in K072370.

(b) (4)



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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b) (4)



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VI. Labeling

Attachment 8 includes the "Instructions for Use" and package labels. The "Instructions for Use" include the indications, contraindications, adverse effects, cautions, warnings, sterilization information and an overview of the surgical technique.

Reviewer Comment: The Indications match the Indications for Use statement. The relevant contraindications and warnings are included and are similar to those included for the Arthrex Tightrope Acromioclavicular device (K052776). The sponsor has only provided a general overview list of the surgical technique. The actual surgical technique guide was found on the sponsor's United Kingdom website at: <http://www.surgicraft.co.uk/pdf/Surgilig%20Surgical%20Technique%202008.pdf>. It appears the sponsor only included the text of the surgical technique in the submission so that the additional pictures and marketing material for the ligament replacement were not included in the submission. The complete surgical technique guide is for the "Surgilig® Acromio-Clavicular Ligament" and is "a synthetic ligament used in acromion-clavicular reconstruction to replace the ligament and recreate the anatomy. It is made of double braided polyester with a patented weave design which acts as a scaffold encouraging tissue in-growth (predominantly scar tissue)." Based on this description it appears the subject device is a ligament replacement. This information will be included in the main deficiency that the device is actually a ligament replacement.

The package labels include the device name, lot, sterile, and symbols for single use only and see package insert.

Reviewer Comment: The sponsor will be advised symbols on package labels are not recognized. The manufacturer's name is not on the package label. The sponsor will be asked to add the manufacturer's name to the package label.

(b) (4)



VII. Sterilization

(b)(4)



(b)(4)



VIII. Biocompatibility

(b)(4)



(b)(4)



IX. Software – Not Applicable

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety – Not Applicable

XI. Performance Testing – Bench

(b) (4)



(b) (4)



(b) (4)



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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8128 207

(b) (4)



(b) (4)



(b) (4)



(b) (4)



(b) (4)



K091207

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b) (4)



(b) (4)



(b) (4)



XII. Performance Testing – Animal – Not Applicable
XIII. Performance Testing – Clinical – Not Applicable

XIV. Substantial Equivalence Discussion

	Yes	No	
1. Same Indication Statement?	X		If YES = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NSE
3. Same Technological Characteristics?		X	If YES = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?	X		If YES = Go To 6
5. Descriptive Characteristics Precise Enough?			If NO = Go To 8 If YES = Stop SE
6. New Types Of Safety Or Effectiveness Questions?		X	If YES = Stop NSE
7. Accepted Scientific Methods Exist?	X		If NO = Stop NSE
8. Performance Data Available?		X	If NO = Request Data
9. Data Demonstrate Equivalence?			Final Decision:

Note: See.

http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the above table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:
2. Explain why there is or is not a new effect or safety or effectiveness issue:
3. **Describe the new technological characteristics:**
The predicate acromioclavicular devices use a suture and buttons for fixation. The subject device is a mesh that is very similar to a ligament replacement.
4. **Explain how new characteristics could or could not affect safety or effectiveness:**
The mesh design will affect the performance of the device and will serve as a scaffold for tissue ingrowth affecting for safety and effectiveness.
5. Explain how descriptive characteristics are not precise enough:
6. **Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:**
The components of the device are all previously cleared. The questions being asked are similar to other acromioclavicular devices; however, if used as a ligament replacement no questions arise and the device is regulated as a Class III PMA device.
7. Explain why existing scientific methods can not be used:
8. **Explain what performance data is needed:**
The sponsor needs to clarify if this is a ligament replacement. The sponsor should also evaluate the construct as a whole.
9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

(b) (4)



(b) (4)



K091207

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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XVI. Contact History

None.

XVII. Recommendation


I recommend the sponsor be sent a request for **Additional Information (AI)** with the deficiencies listed above.

Regulation Number: 21 CFR 888.3030


Regulation Name: Single/Multiple component metallic bone fixation appliances and accessories

Regulatory Class: Class II

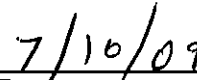
Product Code: HTN



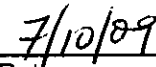
Reviewer



Branch Chief

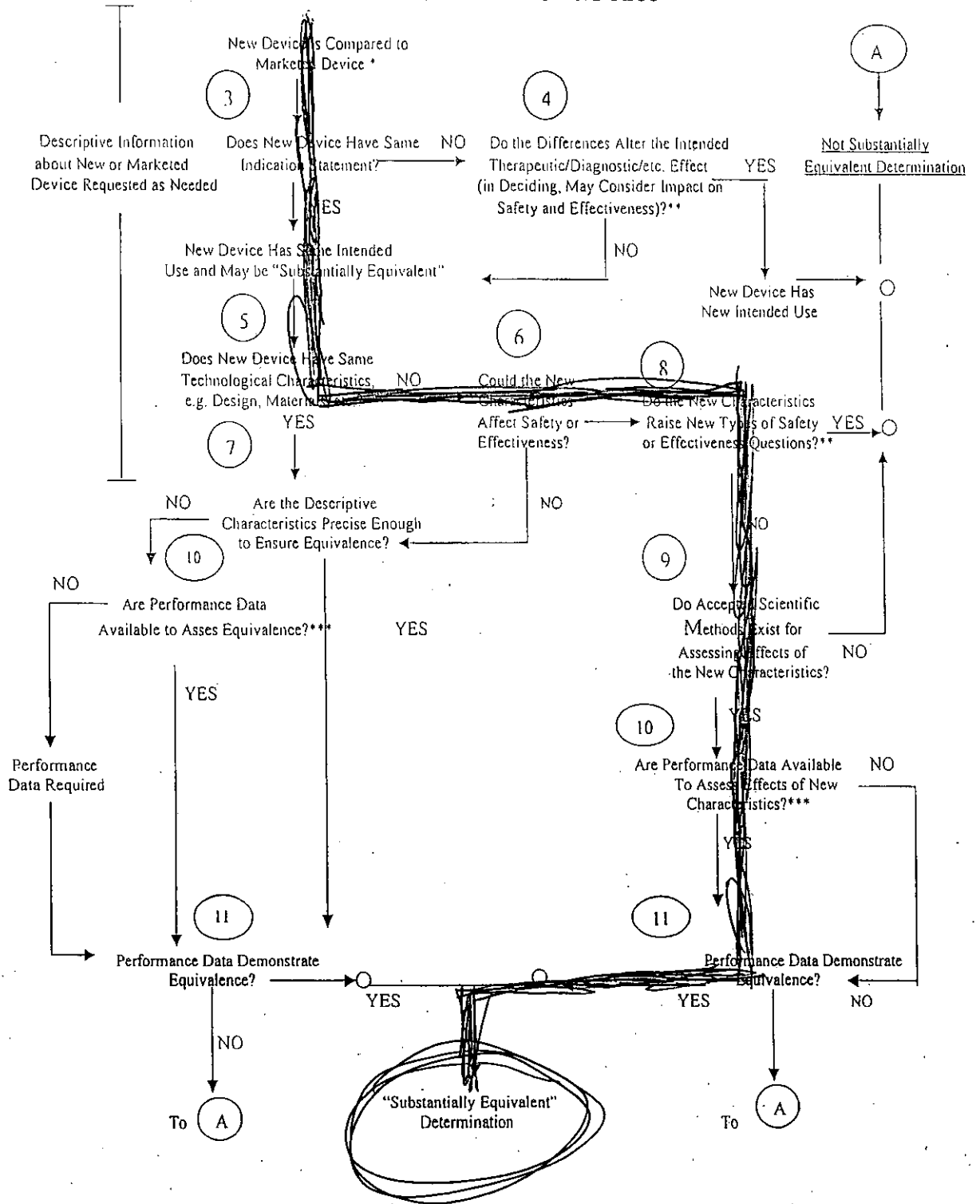


Date



Date

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



❖ 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

❖❖ This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

❖❖❖ Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.



U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

January 06, 2010

SURGICRAFT LTD.
C/O ORGENIX, LLC
111 HILL ROAD
DOUGLASSVILLE, PENNSYLVANIA 19518
UNITED STATES
ATTN: DONALD W. GUTHNER

510k Number: K091207

Product: SURGICRAFT SURGILIG

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff



CRO Services Clinical
Regulatory
Reimbursement

January 5, 2010

FDA CDRH DMC

Office of Device Evaluation, 510(k)
Center of Devices and Radiological Health
Document Mail Center (WO66-0906)
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

JAN 06 2010

Received

KY

RE: K091207/S1 – 510(k) Application – Surgicraft SURGILIG™ AC
Attn: Document Control Clerk

Dear Sir/Madam,

Orgenix, LLC is performing the role of consultant on behalf of:

Surgicraft.

This letter and the Attachments comprise the Sponsor's response (i.e., Supplement 1) to the FDA request for Additional Information dated July 10, 2009. The Sponsor feels they have fully and completely responded in a constructive manner to all comments and noted deficiencies in the review of the 510(k) application K091207. They have also responded to the Advisory (point #6) by including the required language in the product label.

The Sponsor would like to emphasize at the outset that the Sponsor intends to market this device in accordance with the intended use of the FDA-approved Class II device, the Arthrex AC Tightrope Device (K052776), the only designated predicate device. The Sponsor is aware of FDA's concerns regarding off-label use of certain devices. The Sponsor is also aware that many devices, which clearly have additional intended uses when sold outside of the USA, have been approved or cleared by FDA and have been successfully used as labeled to the benefit of US patients. The Sponsor has carefully considered these concerns and has chosen to clearly label the devices intended for US distribution as different from their OUS distributed products, including a distinctly separate name from their *Surgilig* family of products, which will be distributed in the rest of the world. The new name for this product will be the "*Surgicraft LOCKDOWN Acromioclavicular (AC) Device*". All references to ligament repair or ligament function will be eliminated from the labeling of the device distributed in the USA.

In this response the Sponsor has clearly shown in side-by-side testing with a legally marketed predicate device that the *Surgicraft LOCKDOWN Acromioclavicular (AC) Device* is substantially equivalent in function and performance for the identical indications to the Arthrex

111 Hill Road * Douglassville, PA 19518
(646) 460-2984 * (888) ORGENIX * (484) 363-5879 (FAX)
www.orgenix.com

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AC Tightrope Device and, while they differ in design, they are identical in concept, intended use, and performance. The Sponsor has gone to considerable effort to obtain the Arthrex devices in order to comply with FDA's requests for this comparative testing. As presented later in the response, the comparative testing demonstrates substantial equivalence to the Tightrope predicate device.

(b) (4)



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1/5/2010



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1/5/2010

(b) (4)



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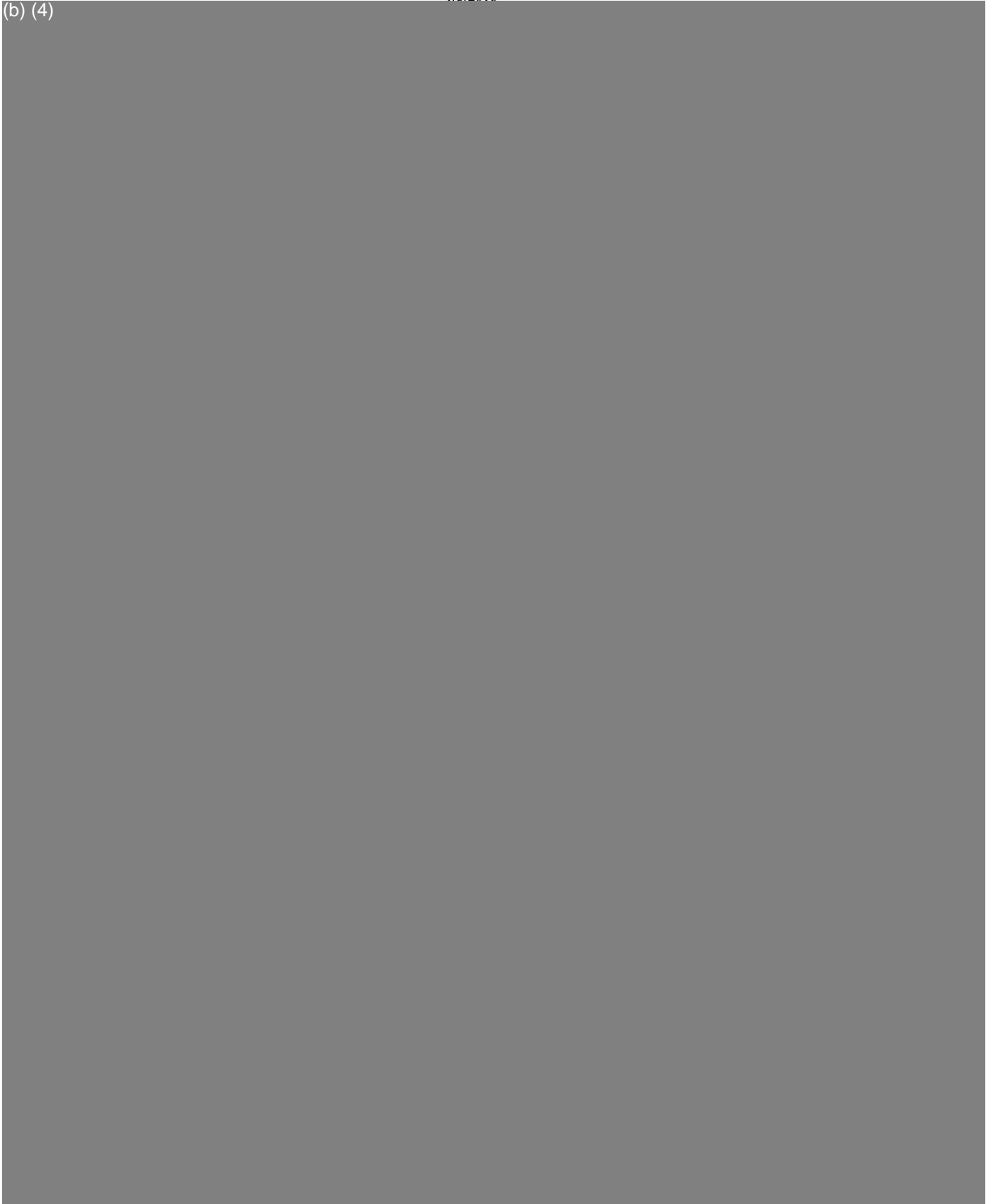
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Page 5 of 10
1/5/2010

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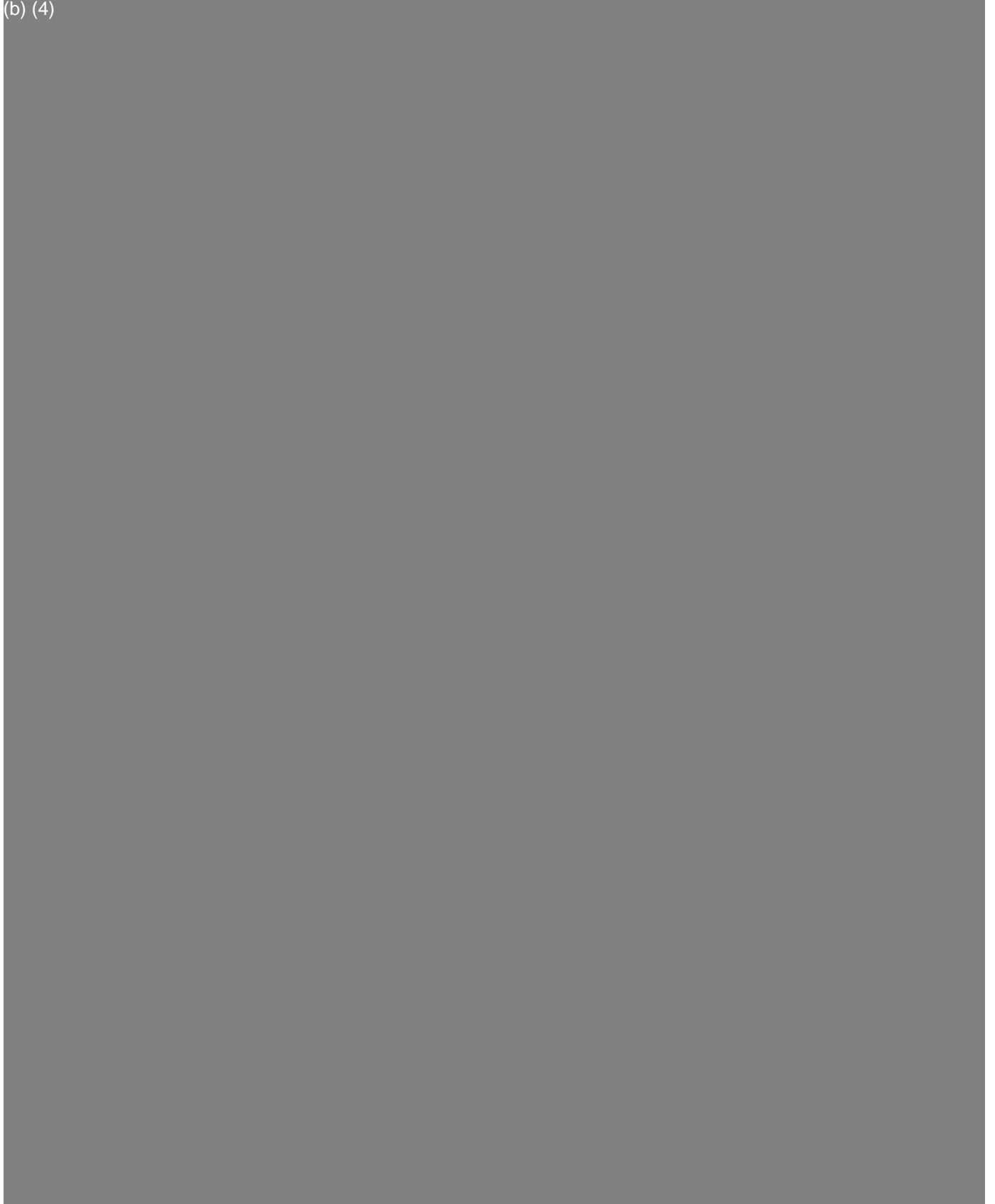
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1/5/2010

(b) (4)



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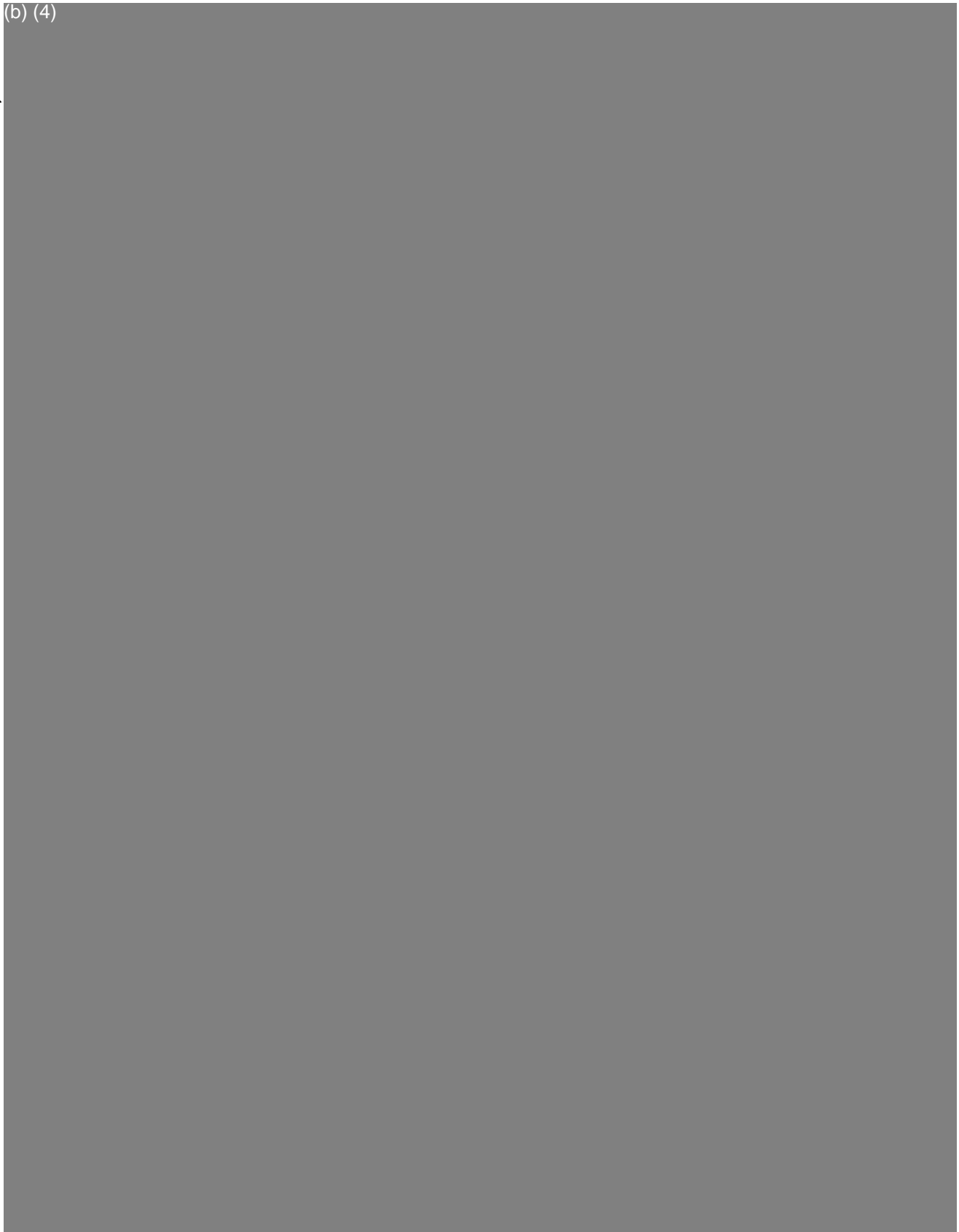
091228 letter.docx
Page 8 of 10
1/5/2010

(b) (4)



091228 letter.docx
Page 9 of 10
1/5/2010

(b) (4)



107

(b) (4)



It has been the intention of the Sponsor to completely respond to the questions raised in this letter. If you have any questions regarding any of the responses, please do not hesitate to ask.

Regards,



Donald W. Guthner for
Surgicraft



Attachment 1

Photos of the Surgicraft LOCKDOWN and Arthrex Tightrope constructs from the cadaveric testing.

Illustrations of the Surgicraft LOCKDOWN and Arthrex Tightrope constructs

Surgical Technique Guide (USA)

Surgicraft LOCKDOWN AC device IFU (USA)

TR SC 031008 Addendum 3 v2 report

(b)(4)

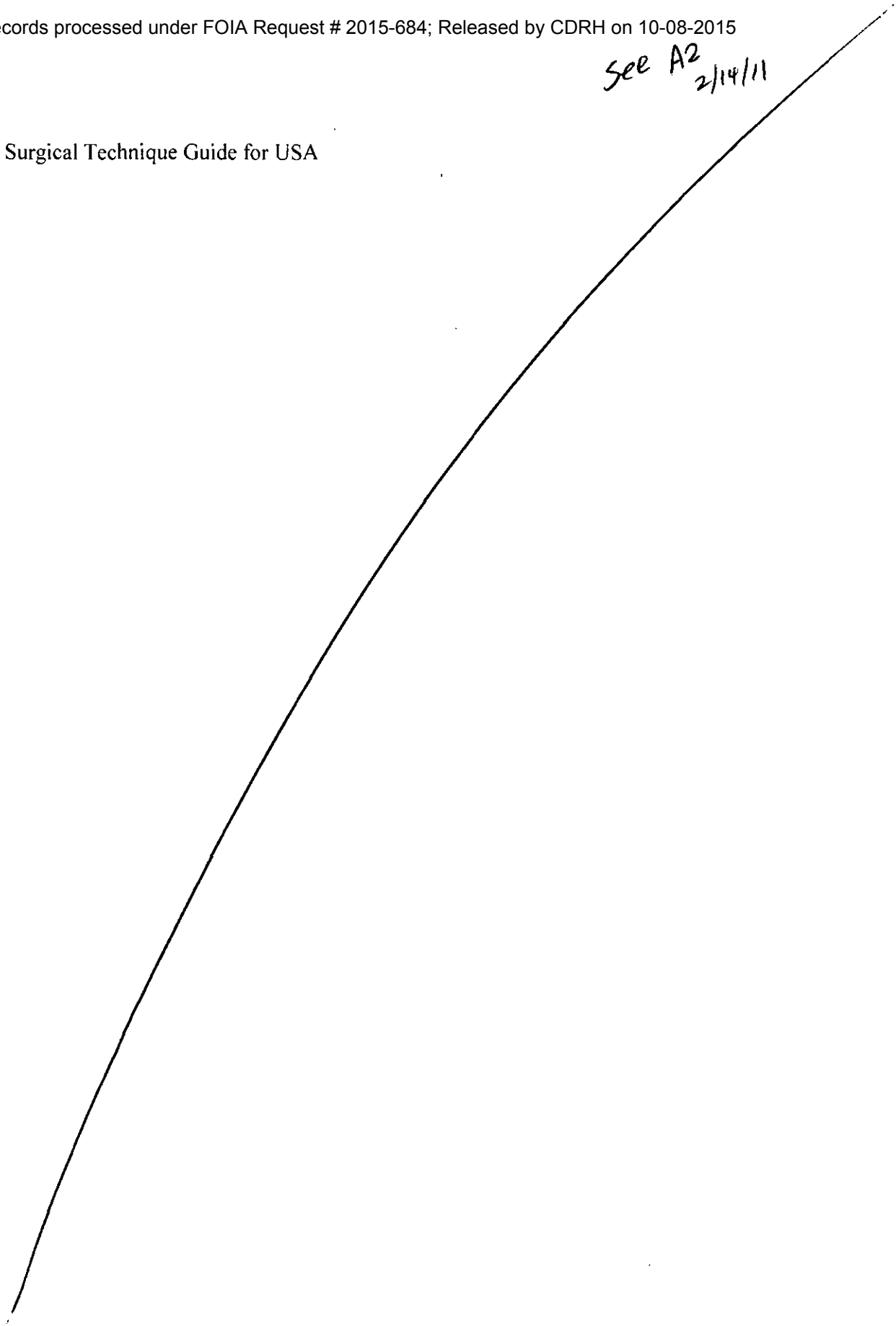


(b)(4)



*see A2
2/14/11*

Updated Surgical Technique Guide for USA



Records processed under FOIA Request # 2015-684; Released by CDRH on 10-08-2015

Records processed under FOIA Request # 2015-684; Released by CDRH on 10-08-2015

Records processed under FOIA Request # 2015-684; Released by CDRH on 10-08-2015

Records processed under FOIA Request # 2015-684; Released by CDRH on 10-08-2015

Records processed under FOIA Request # 2015-684; Released by CDRH on 10-08-2015

Records processed under FOIA Request # 2015-684; Released by CDRH on 10-08-2015

Records processed under FOIA Request # 2015-684; Released by CDRH on 10-08-2015

Records processed under FOIA Request # 2015-684; Released by CDRH on 10-08-2015

Records processed under FOIA Request # 2015-684; Released by CDRH on 10-08-2015

Records processed under FOIA Request # 2015-684; Released by CDRH on 10-08-2015

Revised testing report SC31008

Records processed under FOIA Request # 2015-684; Released by CDRH on 10-08-2015

Records processed under FOIA Request # 2015-684; Released by CDRH on 10-08-2015

Records processed under FOIA Request # 2015-684; Released by CDRH on 10-08-2015

Records processed under FOIA Request # 2015-684; Released by CDRH on 10-08-2015

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Records processed under FOIA Request # 2015-684; Released by CDRH on 10-08-2015

Records processed under FOIA Request # 2015-684; Released by CDRH on 10-08-2015

Updated IFU for USA

Records processed under FOIA Request # 2015-684; Released by CDRH on 10-08-2015

Records processed under FOIA Request # 2015-684; Released by CDRH on 10-08-2015

Attachment 2

Testing Report TR (b)(4)

Records processed under FOIA Request # 2015-684; Released by CDRH on 10-08-2015

Records processed under FOIA Request # 2015-684; Released by CDRH on 10-08-2015

Records processed under FOIA Request # 2015-684; Released by CDRH on 10-08-2015

Records processed under FOIA Request # 2015-684; Released by CDRH on 10-08-2015

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Records processed under FOIA Request # 2015-684; Released by CDRH on 10-08-2015

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Records processed under FOIA Request # 2015-684; Released by CDRH on 10-08-2015

Records processed under FOIA Request # 2015-684; Released by CDRH on 10-08-2015

Records processed under FOIA Request # 2015-684; Released by CDRH on 10-08-2015

Records processed under FOIA Request # 2015-684; Released by CDRH on 10-08-2015

Attachment 3 – refer to Attachment 2

Attachment 4

Predicate Approval letters

Stryker AxSOS bone screw and plate system

K 050512
Special 510(k)

Stryker Plating System Line Extension

MAR 21 2005

Summary of Safety and Effectiveness
Stryker Locked Plating System

Proprietary Name: Stryker Locked Plating System
Common Name: Bone Plate System
Classification Name and Reference: Single/Multiple Component Metallic Bone Fixation Appliances and Accessories, 21 CFR §888.3030
Smooth or Threaded Metallic Bone Fixation Fastener, 21 CFR §888.3040
Proposed Regulatory Class: Class II
Device Product Code: 87 HRS: Plate, Fixation, Bone
87 HWC: Screw, Fixation, Bone
For Information contact: Vivian Kelly, Regulatory Affairs Specialist
Howmedica Osteonics Corp.
325 Corporate Drive
Mahwah, NJ 07430
Phone: (201) 831-5581
Fax: (201) 831-6038
Date Summary Prepared: February 25, 2005

Description:

This Special 510(k) submission is intended to address modifications to the predicate Stryker Plating System.

Intended Use:

The subject and predicate devices are internal fixation plates, screws and accessories of the system. The Stryker Locked Plating System is intended for use in long bone fracture fixation. The new locking plates are indicated for fixation of long bone fractures including but not limited to fractures of the distal radius, the proximal humerus, the distal tibia, proximal tibia and the distal femur.

Substantial Equivalence:

The subject components share the same intended use, and basic design concepts as that of the currently available plates in the Stryker Plating System. Mechanical testing demonstrated comparable mechanical properties to the predicate components.

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Att.² 4 - 1



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAR 21 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Susan Krasny, Ph.D., RAC
Director of Clinical Research/Regulatory Affairs
Howmedica Osteonics Corp.
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K050512
Trade/Device Name: Stryker Locked Plating System
Regulation Numbers: 21 CFR 888.3030, 21 CFR 888.3040
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories, Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Codes: HRS, HWC
Dated: March 26, 2005
Received: March 31, 2005

Dear Dr. Krasny:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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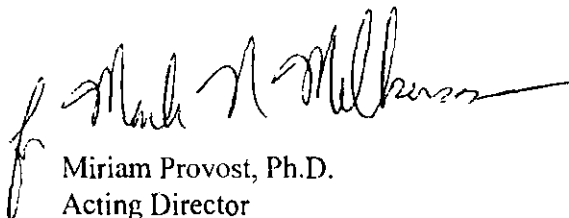
Att. 4 - 2

Page 2 -- Susan Krasny, Ph.D., RAC

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Miriam Provost", with a long horizontal flourish extending to the right.

Miriam Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Stryker Locked Plating System

Indications for Use:

The SPS Monoaxial Locking Plates in the Stryker Locked Plating System are intended for use in long bone fracture fixation. The SPS Monoaxial Locking Plates are indicated for fixation of long bone fractures including but not limited to fractures of the distal radius, the proximal humerus, the distal tibia, proximal tibia and the distal femur.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[Signature]
(Division Sign-Off)

Division of General, Restorative,
and Prosthetic Devices

Page 1 of 1

5/10/2015

K 050512

58

K061012

19 2006

**510(k) Summary of Safety and Effectiveness
AxSOS™ Plus Locking Plate System**

Proprietary Name: AxSOS™ Plus Locking Plate System

Common Name: Bone plates and screws

Classification Name/Reference: Single/multiple component metallic bone fixation appliances and accessories, 21 CFR §888.3030

Device Product Code: 87 KTT

Proposed Regulatory Class: Class II

For Information contact: Francisco Haro, Regulatory Affairs Specialist
Howmedica Osteonics Corp.
325 Corporate Drive
Mahwah, NJ 07430
Phone: (201) 831-5493 Fax: (201) 831-6038

Date Summary Prepared: April 10, 2006

Description

This submission is a line extension to the Stryker® Locked Plating System for various types of locking plates. Plates will be based on the design of the monoaxial plates in the Stryker® Locked Plating System. The subject plates have locking and non-locking holes. All screws will be available sterile and non-sterile. The plates also have holes for standard Kirschner wires to enhance primary plate and fracture fixation or they can be used as suture anchors.

Indications:

The AxSOS™ Plus Locking Plate System is intended for use in long bone fracture fixation. The system is indicated for fixation of long bone fractures including but not limited to fractures of the humerus, tibia, and femur.

Substantial Equivalence:

The AxSOS™ Plus Locking Plate System is substantially equivalent to the Stryker® Locked Plating System in regards to intended use, design, materials, and operational principles as internal fixation components. FEA and mechanical testing was conducted to compare the strength of the new plates to the predicate plates. The results demonstrate that the subject components are substantially equivalent in strength to the predicate components.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 19 2006

Howmedica Osteonics Corporation
% Mr. Francisco Haro
Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K061012

Trade/Device Name: AxSOS™ Plus Locking Plate System

Regulation Number: 21 CFR 888.3030

Regulation Name: Single/multiple component metallic bone fixation appliances and accessories

Regulatory Class: II

Product Code: HRS

Dated: April 10, 2006

Received: April 12, 2006

Dear Mr. Haro:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

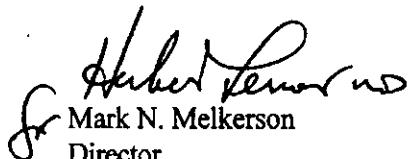
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Page 2 – Mr. Francisco Haro

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): _____

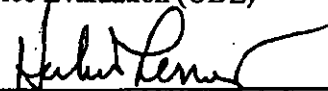
Device Name: AxSOS™ Plus Locking Plate System

Indications for Use:

The AxSOS™ Plus Locking Plate System is intended for use in long bone fracture fixation. The system is indicated for fixation of long bone fractures including but not limited to fractures of the humerus, tibia, and femur.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

**Division of General, Restora
and Neurological Devices**

510(k) Number K061012

Page 1 of 1

K060514

p. 1/2

**Summary of Safety and Effectiveness
Stryker® Plating System Line Extension**

Rev. 17

Proprietary Name: Stryker® Plating System
Common Name: Bone Plate System
Classification Name and Reference: Single/Multiple Component Metallic Bone Fixation Appliances and Accessories, 21 CFR §888.3030
Proposed Regulatory Class: Smooth or Threaded Metallic Bone Fixation Fastener, 21 CFR §888.3040 Class II
Device Product Code: 87 HRS: Plate, Fixation, Bone
87 HWC: Screw, Fixation, Bone
For Information contact: Vivian Kelly, Regulatory Affairs Specialist
Howmedica Osteonics Corp.
325 Corporate Drive
Mahwah, NJ 07430
Phone: (201) 831-5581
Fax: (201) 831-6038
Date Summary Prepared: February 24, 2006

Description:

This Special 510(k) submission is a line extension to address modifications to the Stryker® Plating System (SPS), which includes the SPS Small Fragment Set, the SPS Basic Fragment Set, the SPS Pelvic Set and the Stryker Locked Plating Set. This line extension is to add additional styles of monoaxial plates based on the plates in the SPS Small Fragment Set and the SPS Basic Fragment Set.

Intended Use

The modifications do not alter the intended use of the predicate systems as cleared in their respective premarket notifications. The indications for use for the subject plates are provided below.

Indications

The indications for use for the predicate plates are provided below and in Appendix E. The subject plates and subject accessories have the same indications as cleared their predicates.

SPS Small Fragment Set

The Stryker Plating System, Small Frag Set is indicated for fractures of the metaphysis and/or the diaphysis of the following:

- One third tubular plate: fibula, metatarsals, metacarpals
- Compression plate: radius, ulna, distal tibia, fibula, distal humerus, clavicle
- Oblique T-plate: distal radius
- T-plate: distal radius, calcaneus, lateral clavicle

K060514 P. 2/2

Cloverleaf plate: proximal humerus, distal tibia

Calcaneal plate: calcaneus

Reconstructive plate: humerus, pelvis

Screws are used either to fasten plates or similar devices onto bone, or, as lag screws, to hold together fragments of bone.

SPS Basic Fragment Set

The Basic Fragment Set is intended for use in long bone fracture fixation, Reconstruction plates, wide and narrow straight and waisted compression plates are indicated for fixation of long bone fractures including but not limited to: fractures of the femur, the tibia, the humerus and the pelvis. T-plates, T-buttress plates and L-buttress plates are indicated for fractures at the proximal or distal end of long bones including but not limited to: fractures of the femoral condyles, the tibial plateau, the distal tibia and the proximal humerus.

Substantial Equivalence:

These additional monoaxial components are substantially equivalent to their predicate systems from the Stryker® Plating System in respect to design, intended use, performance and operational principle as internal fixation components.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 17 2006

Howmedica Osteonics Corporation
c/o Ms. Vivian Kelly, RAC
Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K060514

Trade/Device Name: Stryker Plating System

Regulation Number: 21 CFR 888.3030

Regulation Name: Single/multiple component metallic bone fixation appliances
and accessories

Regulatory Class: II

Product Code: HRS, HWC

Dated: February 24, 2006

Received: February 27, 2006

Dear Ms. Kelly:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set


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Page 2 – Ms. Vivian Kelly

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,


for Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K060514

Indications for Use

510(k) Number (if known):

Device Name: Stryker® Plating System

Indications for Use:

SPS Small Fragment Set

The Stryker® Plating System, Small Frag Set is indicated for fractures of the metaphysis and/or the diaphysis of the following:

- One third tubular plate: fibula, metatarsals, metacarpals
- Compression plate: radius, ulna, distal tibia, fibula, distal humerus, clavicle
- Oblique T-plate: distal radius
- T-plate: distal radius, calcaneus, lateral clavicle
- Cloverleaf plate: proximal humerus, distal tibia
- Calcaneal plate: calcaneus
- Reconstructive plate: humerus, pelvis

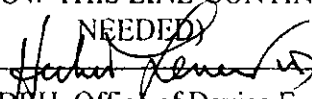
Screws are used either to fasten plates or similar devices onto bone, or, as lag screws, to hold together fragments of bone.

SPS Basic Fragment Set

The Basic Fragment Set is intended for use in long bone fracture fixation, Reconstruction plates, wide and narrow straight and waisted compression plates are indicated for fixation of long bone fractures including but not limited: to fractures of the femur, the tibia, the humerus and the pelvis. T-plates, T-buttress plates and L-buttress plates are indicated for fractures at the proximal or distal end of long bones including but not limited to: fractures of the femoral condyles, the tibial plateau, the distal tibia and the proximal humerus.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF

NEEDED



Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

510(k) Number K060514

APR 12 2006

K060798

P.1/2

**Summary of Safety and Effectiveness
Stryker® Plating System Line Extension**

Proprietary Name: Stryker® Plating System
Common Name: Bone Plate System
Classification Name and Reference: Single/Multiple Component Metallic Bone Fixation Appliances and Accessories, 21 CFR §888.3030
Proposed Regulatory Class: Smooth or Threaded Metallic Bone Fixation Fastener, 21 CFR §888.3040 Class II
Device Product Code: 87 HRS: Plate, Fixation, Bone
87 HWC: Screw, Fixation, Bone
For Information contact: Vivian Kelly, Regulatory Affairs Specialist
Howmedica Osteonics Corp.
325 Corporate Drive
Mahwah, NJ 07430
Phone: (201) 831-5581
Fax: (201) 831-6038
Date Summary Prepared: March 23, 2006

Description:

This Special 510(k) submission is a line extension to address modifications to the Stryker® Plating System (SPS), which includes the SPS Small Fragment Set, the SPS Basic Fragment Set, the SPS Pelvic Set and the Stryker Locked Plating Set. This line extension is to add additional styles of plates based on the plates in the SPS Small Fragment Set and the SPS Basic Fragment Set.

Intended Use

The modifications do not alter the intended use of the predicate systems as cleared in their respective premarket notifications. The indications for use for the subject plates are provided below.

Indications

The indications for use for the predicate plates are provided below. The subject plates and subject accessories have the same indications as cleared their predicates.

SPS Small Fragment Set

The Stryker Plating System, Small Frag Set is indicated for fractures of the metaphysis and/or the diaphysis of the following:

One third tubular plate: fibula, metatarsals, metacarpals
Fibular plate: fibula
Compression plate: radius, ulna, distal tibia, fibula, distal humerus, clavicle
Oblique T-plate: distal radius
T-plate: distal radius, calcaneus, lateral clavicle

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Att. 4 - 14

K060798

p. 2/2

Cloverleaf plate: proximal humerus, distal tibia

Calcaneal plate: calcaneus

Reconstructive plate: humerus, pelvis

Screws are used either to fasten plates or similar devices onto bone, or, as lag screws, to hold together fragments of bone.

SPS Basic Fragment Set

The Basic Fragment Set is intended for use in long bone fracture fixation.

Reconstruction plates, wide and narrow straight and waisted compression plates are indicated for fixation of long bone fractures including but not limited to: fractures of the femur, the tibia, the humerus and the pelvis.

T-plates, T-buttress plates and L-buttress plates are indicated for fractures at the proximal or distal end of long bones including but not limited to: fractures of the femoral condyles, the tibial plateau, the distal tibia and the proximal humerus.

Substantial Equivalence:

These additional components are substantially equivalent to their predicate systems from the Stryker® Plating System in respect to design, intended use, performance and operational principle as internal fixation components.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

APR 12 2006

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Howmedica Osteonics Corporation
c/o Ms. Vivian Kelly
Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K060798

Trade/Device Name: Stryker® Plating System

Regulation Number: 21 CFR 888.3030

Regulation Name: Single/multiple component metallic bone fixation appliances
and accessories

Regulatory Class: II

Product Code: HRS, HWC

Dated: March 23, 2006

Received: March 24, 2006

Dear Ms. Kelly:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

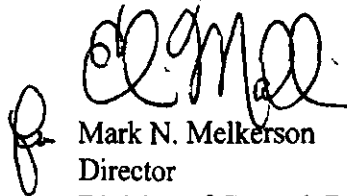
Page 2 – Ms. Vivian Kelly

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K060798

Indications for Use

510(k) Number (if known):

Device Name: Stryker® Plating System

Indications for Use:

SPS Small Fragment Set

The Stryker® Plating System, Small Frag Set is indicated for fractures of the metaphysis and/or the diaphysis of the following:

- One third tubular plate: fibula, metatarsals, metacarpals
- Fibular plate: fibula
- Compression plate: radius, ulna, distal tibia, fibula, distal humerus, clavicle
- Oblique T-plate: distal radius
- T-plate: distal radius, calcaneus, lateral clavicle
- Cloverleaf plate: proximal humerus, distal tibia
- Calcaneal plate: calcaneus
- Reconstructive plate: humerus, pelvis

Screws are used either to fasten plates or similar devices onto bone, or, as lag screws, to hold together fragments of bone.

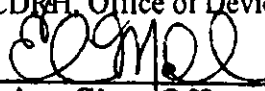
SPS Basic Fragment Set

The Basic Fragment Set is intended for use in long bone fracture fixation. Reconstruction plates, wide and narrow straight and waisted compression plates are indicated for fixation of long bone fractures including but not limited to: fractures of the femur, the tibia, the humerus and the pelvis. T-plates, T-buttress plates and L-buttress plates are indicated for fractures at the proximal or distal end of long bones including but not limited to: fractures of the femoral condyles, the tibial plateau, the distal tibia and the proximal humerus.

Prescription Use X AND/OR Over-The-Counter Use _____
 (Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)
 (PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
 NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1



(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

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**510(k) Summary of Safety and Effectiveness:
AxSOS[®] Stryker Locked Plating System Line Extension of Cable Plugs**

Submission Information

Name and Address of the Sponsor
of the 510(k) Submission

Howmedica Osteonics Corp
325 Corporate Drive
Mahwah, NJ 07430

NOV 20 2009

For Information contact:

Melissa A. Matarese, Regulatory Affairs
Associate
Howmedica Osteonics Corp.
325 Corporate Drive
Mahwah, NJ 07430
Phone: (201) 831-5116
Fax: (201) 831-4116

Date Summary Prepared:

July 15, 2009

Device Identification

Proprietary Name:

AxSOS[®] Stryker Locked Plating System
Line Extension of Cable Plugs

Common Name:

Bone plates and screws

Classification Name and Reference:

Single/multiple component metallic bone
fixation appliances and accessories, 21 CFR
§888.3030

Device Product Code:

87 HRS: Plate, Fixation, Bone

87 HWC: Screw, Fixation, Bone

Description:

This Special 510(k) submission is intended to address modifications to the Stryker Locked Plating System. This line extension is to add additional styles of Cable Plugs. The AxSOS[®] Cable Plug is being modified as part of a line extension of the Stryker Locked Plating System. The AxSOS[®] Locked Plating System currently contains 4mm and 5mm Cable Plugs.

Intended Use:

The AxSOS[®] Stryker Locked Plating System Line Extension of Cable Plugs modifications do not alter the intended use of the predicate systems as cleared in their respective premarket notifications. The indications for use for the subject plates are provided below.

Indications for Use:

The AxSOS[®] SPS Monoaxial Locking Plates in the Stryker Locked Plating system are intended for use in long bone fracture fixation. The AxSOS[®] SPS Monoaxial Locking

K052170 P.2 of 2

AxSOS[®] Stryker Locked Plating System Line Extension of Cable Plugs

Special 510(k)

Plates are indicated for fixation of long bone fractures including the distal radius, the proximal humerus, the distal tibia, proximal tibia and the distal femur.

Statement of Technological Comparison:

The subject and predicate devices are made from Stainless Steel. Functional and mechanical testing demonstrates the comparable mechanical & functional properties of the subject AxSOS[®] Stryker Locked Plating System to the predicate device K050512, K060514, K061012, and K060798.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Howmedica Osteonics Corporation
c/o Ms. Melissa Matarese
Regulatory Affairs Associate
325 Corporate Drive
Mahwah, New Jersey 07430

NOV 20 2009

Re: K092178
Trade/Device Name: AxSOS® Locked Plating System Line Extension of Cable Plugs
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: October 30, 2009
Received: November 5, 2009

Dear Ms. Matarese:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

Page 2 - Ms. Melissa Matarese


CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/industry/default.htm>.

Sincerely yours,



 Mark N. Melkerson
Director Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K092178

Device Name: AxSOS[®] Locked Plating System Line Extension of Cable Plugs

Indications For Use:

The AxSOS[®] SPS Monoaxial Locking Plates in the Stryker Locked Plating system are intended for use in long bone fracture fixation. The AxSOS[®] SPS Monoaxial Locking Plates are indicated for fixation of long bone fractures including fractures of the distal radius, the proximal humerus, the distal tibia, proximal tibia, and the distal femur.

Prescription Use

 X
(Part 21 CFR 801
Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

[Signature]
(Division Sign Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K092178

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Attachment 5

Revised Labeling





FRONT OF BOX LABEL


200 x 75 mm

LOCKDOWN
7cm ACROMIOCLAVICULAR (AC) DEVICE
Material: Polyethyleneterephthalate

REF LD070 **LOT** LOT NUMBER 123456

STERILE R Sterile unless the package is damaged or open.
Method of sterilization - gamma irradiation

 Do not reuse  0086   Use by - year & month 2014-12

 See instructions for use

Rx ONLY Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician

END OF BOX LABEL

REF LD070 LOT NUMBER 123456
LOCKDOWN 7cm (AC) DEVICE
Material: Polyethyleneterephthalate

64 x 19 mm

END OF BOX

SURGICRAFT Manufactured by: Surgicraft
16 The Oaks, Clews Road,
Redditch, UK. B98 7ST
www.surgicraft.co.uk

17/12/09 *AG*

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Att. 5-1

FRONT OF BOX LABEL

LOCKDOWN
L14mm CORTICAL SCREW 3.5mm (SS)
& 7mm x 1mm washer (SS)
Material: Titanium Alloy 6A14V ELI

REF LDSS14 LOT NUMBER 123456
Use By - year & month 2014-12

Sterile unless the package is damaged or open.
Method of sterilization - gamma irradiation
Do not reuse.
See instructions for use
Rx ONLY



0086

Rx ONLY Caution: Federal Law (USA) restricts this device to sale
by or on the order of a physician

76 x 51 mm

END OF BOX LABEL

REF LDSS14 LOT NUMBER 123456
L14mm CORTICAL SCREW 3.5mm (SS)
& 7mm x 1mm washer (SS)
Material: Titanium Alloy 6A14V ELI

64 x 19 mm

END OF BOX

SURGICRAFT Manufactured by: Surgicraft
16 The Oaks, Clews Road,
Redditch, UK. B98 7ST
www.surgicraft.co.uk

17/12/09 AT

Att. 5 - 2

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