Stryker Corporation
Kristi Ashton
Staff Regulatory Affairs Specialist
4100 East Milham Avenue
Kalamazoo, Michigan 49001

January 25, 2018

Re: K172116
Trade/Device Name: Stryker® iVAS® Elite Inflatable Vertebral Augmentation System
(Stryker® iVAS® Elite Balloon Catheter)
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX, NDN
Dated: December 21, 2017
Received: December 26, 2017

Dear Ms. Ashton:

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 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark N. Melkerson -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K172116

Device Name Stryker® iVAS® Elite Inflatable Vertebral Augmentation System (Stryker® iVAS® Elite Balloon Catheter)

Indications for Use *(Describe)*

The Stryker® iVAS® Elite Inflatable Vertebral Augmentation System is intended to be used for the reduction of fractures and/or creation of a void in cancellous bone in the spine. This includes use during percutaneous vertebral augmentation. The system is to be used with cleared spinal Polymethylmethacrylate (PMMA) bone cements and Cortoss® Bone Augmentation Material indicated for use during percutaneous vertebral augmentation procedures, such as kyphoplasty.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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K172116
510(k) Summary

1. Submitter

a. 510(k) Owner:

Stryker Instruments
4100 E. Milham Avenue
Kalamazoo, Michigan 49001
USA
Ph: +1-269-323-7700
Fax: +1-269-324-5412

b. FDA Establishment Registration Number: 1811755

c. Contact Person:

Kristi Ashton
Ph: +1-269-389-5929
Fax: +1-269-389-5412
Kristi.Ashton@Stryker.com

d. Date Submitted: January 24, 2018

2. Subject Device Name

Trade Name: Stryker iVAS® Elite Balloon Catheter
Common Name: Inflatable Bone Tamp
Product Codes: HRX, NDN
Regulation: 888.1100, 888.3017

3. Legally Marketed Predicate Device (s)

Table 5-1 identifies the predicate devices within this premarket notification.

Table 5-1-Predicate Devices

Predicate Devices	510(k)	Product Code	Manufacturer
11G 15MM iVAS® Balloon Catheter **Primary Predicate**	K130430	HRX NDN	Stryker Instruments
10G 15MM iVAS® Balloon Catheter **Secondary Predicate**	K123942	HRX NDN	Stryker Instruments
10G 15mm Kyphon Express II Inflatable Bone Tamp **Secondary Predicate**	K123771	HRX NDN HXG	Medtronic

4. Device Description

The Stryker iVAS ® Elite Balloon Catheter is a bone tamp with an inflatable component at the distal end. The balloon is inflated to create a void within the vertebral body. It is used with various accessories during vertebral augmentation.

When the balloon is inflated with radiopaque fluid, the balloon expands axially and radially. Two radiopaque markers are fixed near the distal end of the balloon to show the location of the balloon during placement. The balloon is coated with silicone to assist with insertion of the catheter into the access needle.

The patient contacting components of the device such as the balloon, catheter, catheter coating, lubricant and radiopaque material are externally communicating tissue/bone/dentin-limited contact ≤24 hrs.

Associated Accessories include:

- Access cannula/stylet
- Syringe
- Inflator
- Hand Drill
- Coaxial Cement Tube

5. Principles of Operation / Mechanism of Action

The balloon catheter is the functional part of the device that creates a cavity and reduces the fracture. The balloon is designed to create a cavity by compressing cancellous bone and/or moving cortical bone as it inflates. After manufacturing, the balloon is covered with a protector called a sheath that the physician will remove prior to performing a procedure. Radiopaque markers provide for fluoroscopic visualization of the vertebral balloon prior to filling it with contrast media. The radiopaque balloon markers are located within the balloon.

After placing the access cannula into the fractured vertebral body, the physician places the access cannula and stylet in the desired location within the vertebral body, creating a channel for the balloon. The stylet is then removed, leaving the cannula in place. The deflated balloon is inserted through the access cannula. Contrast medium is injected into the balloon to inflate it. As the balloon inflates, it moves and compresses the cancellous bone, creating a void. The balloon is deflated and removed before cement injection takes place. Cement is then injected through the access cannula into this space.

5. Intended Use/Indications for use

The Stryker iVAS® Elite Inflatable Vertebral Augmentation System is intended to be used for the reduction of fractures and/or creation of a void in cancellous bone in the spine. This includes use during percutaneous vertebral augmentation. The system is to be used with cleared spinal Polymethylmethacrylate (PMMA) bone cements and Cortoss®

Bone Augmentation Material indicated for use during percutaneous vertebral augmentation procedures, such as kyphoplasty.

6. Comparison of Technological Characteristics with the Predicate Device

At a high level, the subject and predicate devices are based on the following same technological elements:

- The subject and the predicate devices are identical in that they are intended to create a void and reduce a fracture.
- The subject and the predicate devices are identical in that the surgical method is percutaneous.
- The subject and the predicate devices are identical in that the method of inflation is through the use of a syringe and inflator.
- The subject and the predicate devices have an identical tamp size of 15mm.
- The subject and the predicate devices include a proximal balloon connection to the outer shaft of the balloon.
- The subject and the predicate devices utilize two radiopaque balloon markers inside the balloon for visualization under fluoroscopy.
- The subject and the Stryker predicate devices include the use of the same sliding pin material.
- The subject and the Stryker predicate devices utilize an equivalent balloon material.
- The subject and the predicate devices have an equivalent balloon lubricant to assist in the insertion of the device.
- The subject and predicate devices are all single-use devices.
- The subject and predicate devices utilize depth markers.

The following technological differences exist between the subject and predicate devices:

- The subject and the predicate devices have nominal differences in their balloon diameters.
- The subject and predicate devices have nominal differences in the length of the catheter tube.
- The subject device has a slightly greater inflation volume as compared to the iVAS ® 11G Balloon Catheter and the Express II Balloon Catheter.
- The subject and the predicate devices have different rated balloon inflation pressures. The subject device has a balloon inflation pressure of 808psi. The Stryker predicate has a balloon inflation pressure of 400psi. The Kyphon Express II has a balloon inflation pressure of 700psi.

Biocompatibility:

Biocompatibility testing was performed following the recommendations of ISO 10993-1 and FDA Guidance (Use of International Standard ISO- 10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" June 2016) as appropriate for limited exposure (≤24 hours) externally communicating, tissue/bone/dentin devices.

All biocompatibility testing met the requirements of the respective test method, thus supporting the biocompatibility of the subject device iVAS ® Elite Balloon Catheter.

The following testing data was provided in support of the substantial equivalence determination.

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity
- Chemical Characterization

The biocompatibility testing listed above confirms that the subject device is non-sensitizing, non-irritating and non-toxic (cytotoxic and systemic). The biocompatibility testing for the subject device Stryker iVAS ® Elite Balloon Catheter met all acceptance criteria deeming this to be a biocompatible medical device.

Bench:

The following testing data was provided in support of the substantial equivalence determination.

- Insertion and Retraction Force was performed to show the force required to insert and remove the catheter into the access needle. The subject device met all acceptance criteria.

- Tensile Force Testing was performed to determine a measurement of the force required to pull the subject device to the point of failure. The subject device met all acceptance criteria.

- Length to Diameter testing was performed on the subject device to verify the inflation shape the balloon naturally wants to take without the influence of fixtures or simulated bone. The subject device met all acceptance criteria.

- Unconstrained Burst was performed to verify that the balloon meets a minimum open air inflation volume of 5 cc. The subject device met all acceptance criteria.

- Constrained Burst was performed to simulate the user inflating the balloon beyond the maximum rating stated in the Instructions for Use. The subject device met all acceptance criteria.

- One-way Valve Torque was performed to verify that the luer connector and connection between the luer connector to one-way valve is sufficiently strong to allow for attachment and removal of the Inflator. The subject device met all acceptance criteria.

- Accelerated Aging Testing was performed to verify that the balloon catheter meets the requirements for general use in a balloon-assisted vertebral augmentation procedure after accelerated aging for 18 months. The subject device met all acceptance criteria.

- Silicone Infrared Analysis was performed to prove equivalence between the subject device and Stryker predicates. This analysis demonstrates that the silicones are equivalent.

- Cadaveric testing was performed and demonstrated that increased bone density can exist and can create for a more difficult inflation, requiring pressures >700 psi in order to reach the clinical stopping point of the physician.

The following testing was adopted from K093419:

- Catheter Flexibility Testing and Validation of flexibility testing was performed to measure the following items:
  - time required to deflate 5cc of contrast from within balloon
  - force required to bend the proximal end that protrudes above the access cannulas
- ➢ The subject device met all acceptance criteria.

- Cold Age Testing-was performed to verify that the subject device meets the constrained and unconstrained requirements after being conditioned for 7days at extreme cold temperature of 40^0F and 50% RH. The subject device met all acceptance criteria.

The acceptance criteria for the subject device are similar to the acceptance criteria for the predicate devices, demonstrating equivalence of the subject device to the predicate balloon catheter devices.

8. Clinical Testing
No clinical testing was deemed necessary for this 510(k).

9. Substantial Equivalence Conclusion
The Stryker iVAS® Elite Balloon Catheter is substantially equivalent in intended use, technological characteristics, and safety and effectiveness to the Stryker iVAS® Balloon Catheters (K130430 and K123942) and the Kyphon Express II Inflatable Bone Tamp (K123771). The subject and predicate devices have the same fundamental scientific technology, basic design and clinical applications.

The performance testing proves that the subject device has the same functional characteristics as the predicate devices. Cadaveric testing demonstrated the need for a robust balloon with an inflation pressure of >700psi in order to adequately inflate the balloon to create a void.

A risk analysis, supported by clinical literature, was provided to address adverse events associated with kyphoplasty. The referenced literature in the risk assessment provides support that the causes of adverse events related to kyphoplasty are multi-factorial, but do not include high balloon inflation pressure as a causal factor.

The modifications to the Stryker iVAS® Elite Balloon Catheter do not raise any new safety and effectiveness concerns when compared to similar devices which are already legally marketed. Therefore, the Stryker iVAS® Elite Balloon Catheter is substantially equivalent to the Stryker iVAS ® Balloon Catheters and Kyphon Express II Inflatable Bone Tamp.