Huizhou Foryou Medical Devices Co., Ltd.
Junfeng Zhang
Development Engineer
North Shangxia Rd., Dongjiang Hi-tech Industry Park
Huizhou, 516005 Cn

January 24, 2018

Re: K173196
Trade/Device Name: SUNTOUCH Dental Dressing
Regulatory Class: Unclassified
Product Code: MGQ
Dated: September 29, 2017
Received: October 2, 2017

Dear Junfeng Zhang:

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,

Mary S. Runner -S

For
Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental 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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K173196

Device Name
SUNTOUCH® Dental Dressing

Indications for Use *(Describe)*
SUNTOUCH® Dental Dressing is intended for use as a wound dressing in extraction sites, and may be used as a wound dressing for the temporary management of oral surgical wounds, such as operative, postoperative and traumatic injuries.

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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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# 510(k) Summary

**510(K) Number (if known): K173196**

**1. Submitter Identification:**

Huizhou Foryou Medical Devices Co., Ltd.

North Shangxia Rd., Dongjiang Hi-tech Industry Park, 516005, Huizhou, P. R. China.

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Email: jfzhang@foryougroup.com

Summary day: 01/24/2018

**2. Subject Device Identification:**

Type of 510(k) submission: Traditional

Trade Name: SUNTOUCH® Dental Dressing

Common Name: Dental Dressing

Classification Name: Dressing, Wound And Burn, Hydrogel W/Drug And/Or Biologic

Product Code: MGQ

Regulation Number: Unclassified

Review Panel: General & Plastic Surgery

**3. Primary Predicate Device Identification**

510(k) Number: K090612

Product Name: Benacel® Dental Dressing

Manufacturer: Unicare Biomedical, Inc.

## 4. Device Description

SUNTOUCH® Dental Dressing is made from biocompatible regenerated cellulose, chemically treated to become water-soluble, contains no chemical additives. Upon contact with moist oral wound, the material dissolves and transforms into a gelatinous material. By applying gentle pressure at this time, the material will adhere to the wound and form a barrier, protecting the wound from further irritation. SUNTOUCH® Dental Dressing dissolves in a few days and is safe if swallowed. Excess dressing material may be removed by rinsing with sterile water or saline solution.

The dressings are sterilized with Sterility Assurance Level (SAL) of $10^{-6}$.

## 5. Intended Use Statement

SUNTOUCH® Dental Dressing is intended for use as a wound dressing in extraction sites, and may be used as a wound dressing for the temporary management of oral surgical wounds, such as operative, postoperative and traumatic injuries.

## 6. Comparison to Predicate Device

SUNTOUCH® Dental Dressing is compared with the following Predicate Device in terms of intended use, design, material, size, structure, performance test, biocompatibility test and animal test.

510(k) Number: K090612
Product Name: Benacel® Dental Dressing
Manufacturer: Unicare Biomedical, Inc

The following table (Table 5.1) shows similarities and differences of technology characteristics between proposed device and predicate device.

Table 5.1 Comparison of Technology Characteristics of Proposed and Predicate Device

| Item | Proposed Device | Predicate Device (K090612) |
|---|---|---|
| Indication for Use | SUNTOUCH® Dental Dressing is intended for use as a wound dressing in extraction sites, and may be used as a wound dressing for the temporary management of oral surgical wounds, such as operative, postoperative and traumatic injuries. | Benacel® Dental Dressing is intended for use as a wound dressing in extraction sites and the management of alveolar osteitis (dry socket) and may be used as a wound dressing for the temporary management of oral surgical wounds, such as operative, postoperative, donor sites, and traumatic injuries. Benacel® Dental Dressing may also be used as a wound dressing for the management and protection of oral lesions, including sores, ulcers, and injuries, such as cuts, lacerations and abrasions of the oral mucosa. |
| Prescription/ OTC | Prescription | Prescription |
| Mechanism | When contact with moist oral mucosa, the material dissolves and transforms into a gelatinous material. By applying gentle pressure at this time, the material will adhere to the wound and form a barrier, protecting the wound from further irritation and pain. | When contact with moist oral mucosa, the material dissolves and transforms into a gelatinous material. By applying gentle pressure at this time, the material will adhere to the wound and form a barrier, protecting the wound from further irritation and pain. |
| Material | Regenerated cellulose | Regenerated cellulose |
| Size | 5mm×7mm(plug), 6mm×8mm(plug), 11mm×11mm(pack), 15mm×15mm(pack), 19mm×19mm(pack), 30mm×30mm(sheet) | 5mm x 7mm(plug), 6mmx8mm(plug), 15mm x 15mm(sheet), 50mm x 50mm(sheet) |
| Structure | Textile | textile |
| Fabric Type | Knitted Fabric | Woven Fabric |

| | | |
|---|---|---|
| Single Use | Yes | Yes |
| Sterilization | Radiation | Radiation |

The indication for use of proposed device is included in that of predicate device, therefore, this difference is considered not to affect the Substantially Equivalency (SE) between the proposed and predicate device.

The proposed device has more size specifications than that of predicate device. The size will not affect the function and performance of the product. And more size will give user more choice per wound area. Therefore, this difference is considered not to affect the Substantially Equivalency (SE) between the proposed and predicate device.

The fabric type of the proposed is knitted fabric, and the fabric type of the predicate device is woven fabric. But the different of fabric type do not affect the safe and effective performance.

SUNTOUCH® Dental Dressing and its predicate device are both made from regenerated cellulose, and utilize the same mechanism. They are both indicated for protecting the oral wound.

We recorded the infrared spectra of SUNTOUCH® Dental Dressing and Benacel® Dental Dressing. The almost identical spectra indicated both devices are very similar in chemical structure.

The performance tests between proposed device and predicate device were conducted to evaluate the properties of the proposed and predicate device. The following parameters were monitored: Water absorbency, Gelation time, Weight per unit area, Content of sodium (USP Carboxymethylcellulose Sodium), Degree of polymerization (ASTM D 1795), Heavy metals (USP <231>), Chloride, pH value (USP <791>), Degree of etherification (ASTM D

1439) and Adhesion force. The results showed that the proposed and predicate device were substantially equivalent.

SUNTOUCH® Dental Dressing was evaluated in a porcine (minipig) model to evaluate the local reaction and absorption time as compared to predicate device. The results showed that the proposed and predicate device were substantially equivalent.

The biocompatibility testing was conducted to confirm the safe performance of SUNTOUCH® Dental Dressing. The biocompatibility tests (Table 5.2) were conducted following procedures outlined in the respective consensus standards, and the results met all relevant requirements in the test standards.

Table 5.2 Biocompatibility Test

| Description | proposed device |
|---|---|
| Ames | No Toxic Effect (ISO 10993-3) |
| In vitro Mammalian Chromosome Aberration | |
| In Vivo Mammalian Erythrocyte Micronucleus | |
| Cytotoxicity | No Toxic Effect (ISO10993-5) |
| Subcutaneous implantation | No Effect (ISO 10993-6） |
| Skin Sensitization | No Effect (ISO 10993-10) |
| Intracutaneous Reactivity | |
| Oral Mucosa Irritation | |
| Acute Systematic Toxicity | No Effect (ISO 10993-11) |
| Pyrogenicity | No Effect (ISO 10993-11) |
| Subacute Systematic Toxicity | No Effect (ISO 10993-11) |

## 7. Substantial Equivalent Statement

Based on the comparisons of intended use, design, materials, size, structure, performance test, animal test and biocompatibility test.

SUNTOUCH® Dental Dressing is substantial equivalent to its predicate device.