DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 27, 2015

Sarasota Medical Products
Dr. Walter Leise, III
CEO/President
1451 Sarasota Center Boulevard
Sarasota, Florida 34240

Re: K151186
Trade/Device Name: Stay Fresh Hydrocolloid
Regulatory Class: Unclassified
Product Code: FRO
Dated: October 30, 2015
Received: November 2, 2015

Dear Dr. Leise:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical 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)*
K151186

Device Name
Stay Fresh Hydrocolloid

Indications for Use *(Describe)*

Rx: Under the supervision of a healthcare professional, the Stay Fresh Hydrocolloid dressing is intended for use as a primary dressing for exuding wounds that acts as a barrier to bacterial penetration, for use on first and second degree burns, surgical wounds, pressure ulcers, dermal ulcers, as well as minor cuts, abrasions, lacerations.

OTC: The Stay Fresh Hydrocolloid dressing acts as a barrier to bacterial penetration and is indicated for first aid to cover minor cuts, minor abrasions, and minor lacerations.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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

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K151186:
510(K) SUMMARY
FOR
SARASOTA MEDICAL PRODUCTS
STAY FRESH HYDROCOLLOID

1. SUBMITTER/510(K) OWNER

Sarasota Medical Products, Inc.
1451 Sarasota Center Blvd,
Sarasota, Fl. 34240
Phone 941-377-1451
Fax 941-377-1450

Contact Person: Dr. Walter Leise, III
CEO/President
Phone: (941) 377-1451 Ext. 222

Date Prepared: October 30, 2015

2. DEVICE NAME

Proprietary Name: *Stay Fresh* Hydrocolloid
Common/Usual Name: Hydrocolloid Dressing
Product Code: FRO
Classification Name: Dressing, Wound, Drug
Device Class: Unclassified

3. PREDICATE/REFERENCE DEVICES

Primary Predicate Device	K050032 & K081274 Euromed SureSkin Silver Wound Dressings and SureSkin Silver Bandage
Reference Devices	Sarasota Medical Products' *Fortaderm* MTMA Hydrocolloid
	K121898, Quick-Med Technologies, Inc. *Stay Fresh* Skin Fold Management Textile
	K083113 ACTICOAT FLEX 7 Dressing

4. DEVICE DESCRIPTION

Device Identification:
Sarasota Medical Products hydrocolloid dressing adhesive formulations are composed of naturally occurring substances that turn into a gel when they come into contact with wound fluid. Superabsorbent particles are embedded in an inert polymer matrix that provides the desired level of cohesiveness required to prevent leaving any residue in the wound.

The outer most layer of the dressing is covered by a polyurethane film that reinforces the dressing's barrier properties and helps to reduce friction on clothing, bedding, and opposing extremities. When placed over a wound, these dressings create a moist environment. This environment has been shown to help to facilitate the removal of debris and protect the wound against bacteria and other external contaminants.

Shapes and Dimensions of *Stay Fresh* Hydrocolloid Dressings

SKU	Description	Color	Size	Quantity
170405010504	Rectangle/Std	Off-white	2" x 4"	20 per box
170505010504	Rectangle/Std	Off-white	2" x 6"	10 per box
170605010503	Rectangle/Thin	Off-white	2" x 8"	10 per box
170605010504	Rectangle/Std	Off-white	2" x 8"	10 per box
170205010504	Square/Thin	Off-white	2" x 2"	20 per box
170105010504	Square/Std	Off-white	4" x 4"	10 per box
170105010503	Square/Thin	Off-white	4" x 4"	10 per box
170305010504	Square/Std	Off-white	6" x 6"	10 per box
170305010503	Square/Thin	Off-white	6" x 6"	10 per box
170705010504	Oval/Std	Off-white	4" x 6"	10 per box
170805010503	Oval Spot/Thin	Off-white	1 3/4" x 1 1/2"	8 per box
170905010503	Small finger & toe/Thin	Off-white	3/4" x 2 3/4"	8 per box
171005010503	Small Rectangle/Thin	Off-white	3/4" x 1 5/8"	6 per box
171105010503	Large finger & toe/Thin	Off-white	1 1/4" x 2 3/4"	10 per box
171405010503	Small Rectangle/Thin	Off-white	1 1/4" x 2 3/4"	6 per box
171205010503	Oval Spot 2/Thin	Off-white	1 5/8" X 2 3/4"	6 per box
171305010503	Knee & Elbow	Off-white	3" X 3"	4 per box

Device Characteristics:

. The *Stay Fresh* Hydrocolloid includes sequestered hydrogen peroxide (0.2 to 0.35% by weight). The sequestered hydrogen peroxide is an effective and safe antibacterial agent that protects the dressing. The role of antibacterial agents in wound dressings is: 1) to reduce the incidence of bacterial colonization within the dressing and 2) to provide a potential barrier to bacterial entry into the wound. The *Stay Fresh* Hydrocolloid is effective in controlling growth of bacteria commonly found to populate dressings. The outer thermoplastic layer is effective at providing a physical barrier to bacterial entry into the wound.

The *Stay Fresh* Hydrocolloid dressing will be supplied sterile. Sterilization will be achieved by gamma radiation at 25 Kgy in accordance with ISO 11137 and ISO 14385.

Brief Description of Device:

The *Stay Fresh* Hydrocolloid includes sequestered hydrogen peroxide (0.2 to 0.35% by weight). The sequestered hydrogen peroxide is an effective and safe antibacterial agent that protects the dressing. The *Stay Fresh* Hydrocolloid is effective in controlling growth of bacteria commonly found to populate dressings. The outer thermoplastic layer is effective at providing a physical barrier to bacterial entry into the wound.

5. INTENDED USE

Rx: Under the supervision of a healthcare professional, the *Stay Fresh* Hydrocolloid dressing is intended for use as a primary dressing for exuding wounds that acts as a barrier to bacterial penetration, for use on first and second degree burns, surgical wounds, pressure ulcers, dermal ulcers, as well as minor cuts, abrasions, lacerations.

OTC: The *Stay Fresh* Hydrocolloid dressing acts as a barrier to bacterial penetration and is indicated for first aid to cover minor cuts, minor abrasions, and minor lacerations.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The purpose of this 510(k) is to obtain clearance to market the *Stay Fresh* Hydrocolloid dressing as a wound dressing.

The *Stay Fresh* Hydrocolloid is substantially equivalent to the predicate devices with respect to design, material composition, device characteristics and intended use.

We have chosen Euromed's SureSkin Silver dressing as our primary predicate device. Specifically, these are the SureSkin III with Silver Wound Dressing (K050032 for Rx) and SureSkin Silver Bandage (K081274 for OTC) The SureSkin dressings are composed of a hydrocolloid material and silver, which are in contact with the wound, and an occlusive polyurethane backing. Hydrocolloid wound dressings are composed of very similar components, including CMC, in different ratios to attain the desired tack, wear-time, and absorbance of the final dressing. These slight differences in formulation do not affect the safety or effectiveness of the final device.

The key difference between the technological characteristics of the proposed and predicate devices is the antibacterial agent used to protect the dressings from bacterial contamination. The primary predicate and reference devices contain silver, while the proposed device contains sequestered hydrogen peroxide. The data presented in this submission substantiates the safety and efficacy of the proposed product to overcome any concern regarding the technological differences of the proposed and predicate devices in support of a substantial equivalence decision.

We have chosen Sarasota Medical Products' *Fortaderm* MTMA (Moderate Tack/Medium Absorption) non-antibacterial hydrocolloid as a reference device. The *Fortaderm* MTMA adhesive dressing is an occlusive dressing whose material composition is identical to the *Stay Fresh* Hydrocolloid, with the same design, physical properties and intended use. Both dressings are intended to cover a wound and to provide or support a moist wound environment. The

components used to produce the dressings are identical, so physical properties, including tack, wear-time, and absorbance of the final dressings are equivalent.

The key difference between the proposed device and this reference device is the inclusion of sequestered hydrogen peroxide (0.2 to 0.35% by weight) in the proposed device. The sequestered hydrogen peroxide is a safe and effective antibacterial agent that protects the dressing from bacterial contamination.

An additional secondary reference device, Smith & Nephew's Acticoat Flex 7 (K083113) was chosen as an equivalent device that was available to be used in a comparative porcine wound healing study. The Acticoat device is a highly conformable dressing that contains nanocrystalline silver, which provides a microbial barrier for up to 7 days.

A third reference device has been chosen for its technological similarity to the proposed dressing. The QMT *Stay Fresh* Skin Fold Management Textile, cleared under K121898, uses the same active antibacterial agent, hydrogen peroxide, to achieve its intended use of reducing bacterial populations in the substrate.

The proposed device has the same intended use as the primary predicate device as they are both intended to cover a wound and to provide or support a moist wound environment. Data is presented in this submission to substantiate both the safety and efficacy equivalence of the proposed and predicate devices.

7. PERFORMANCE TESTING

The *Stay Fresh* Hydrocolloid dressing has been subjected to testing to assess the biocompatibility, as well as the physical and antibacterial performance of the device, to establish its safety and efficacy. Specifically, the following tests have been performed to support the 510(k) submission:

Biocompatibility Testing

- Cytotoxicity (Agar Diffusion Direct Contact Method)
- Irritation (Primary Skin Irritation)
- Sensitization (Buehler Test)

Wound Healing Study

- Porcine wound healing model
- Full and partial thickness wounds, evaluated for 14 and 6 days respectively
- Includes comparison to predicate and reference devices

Physical Testing & Inspection

- Physical inspection (dispersion, lamination, weight, and thickness)
- Tack (probe tack, 90° peel, and rolling ball)
- Absorbance (@ 4 hr and @ 24 hr)
- Hydrogen peroxide concentration (permanganate titration)
- Final product packaging and inspection

Antibacterial Efficacy Testing

Efficacy testing (QMT 03-2013 - modified ASTM E2180-01)
Minimum Effective Concentration (MEC) determination

Bacterial Barrier Testing

Barrier Test Protocol

8. CLINICAL TESTING

Clinical testing was not performed to support the 510(k) for the *Stay Fresh* Hydrocolloid dressing. Non-clinical testing demonstrates substantially equivalent safety and efficacy as compared to the predicate device.