DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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July 1, 2016

ABIGO Medical AB
% Ms. Deborah Lavoi Grayeski
Senior Project Manager
M Squared Associates, Inc.
575 8th Avenue, Suite 1212
New York, New York 10018

Re: K153674
Trade/Device Name: Sorbact Foam Gentle Border, Sorbact Superabsorbent
Regulatory Class: Unclassified
Product Code: FRO
Dated: June 2, 2016
Received: June 6, 2016

Dear Ms. Grayeski:

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)*
K153674

Device Name
Sorbact® Absorbent Dressings
(Sorbact® Foam Gentle Border, Sorbact® Superabsorbent)

Indications for Use *(Describe)*

Rx.: Sorbact® Foam Gentle Border is indicated for use in the management of moderately exuding partial to full thickness wounds (including clean, colonized, contaminated, or infected wounds): chronic wounds (venous and arterial ulcers, diabetic ulcers and pressure ulcers), postoperative dehisced wounds and traumatic wounds.

Rx.: Sorbact® Superabsorbent is indicated for use in the management of heavily exuding partial to full thickness wounds (including clean, colonized, contaminated, or infected wounds): chronic wounds (venous and arterial ulcers, diabetic ulcers and pressure ulcers), postoperative dehisced wounds and traumatic wounds.

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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"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 number."

SECTION 5

510(k) Summary

I. SUBMITTER	
Submitter:	ABIGO Medical AB Ekonomivägen 5 SE-436 33 Askim Sweden Phone: +46 31 748 49 50 Fax: +46 31 68 39 51
Correspondent Contact:	Deborah Lavoie Grayeski M Squared Associates, Inc. 575 8th Avenue, Suite 1212 New York, NY 10018 USA Office: 703-562-9800x250 Mobile: 202-550-7395, Fax: 703-562-9797 Email: dgrayeski@msquaredassociates.com
Date Prepared:	December 18, 2015
II. DEVICE	
Trade Name:	Sorbact® Absorbent Dressings (Sorbact® Foam Gentle Border, Sorbact® Superabsorbent)
Common Name:	Wound Dressing
Regulatory Class:	Unclassified (Pre-amendment)
Review Panel:	General & Plastic Surgery
Product Code:	FRO
III. PREDICATE DEVICES	
K143151, Cutimed® Sorbact® Wound Dressings, BSN medical GmbH K063059, Sorbact® Wound Dressings, ABIGO Medical AB	

IV. DEVICE DESCRIPTION

Sorbact® Absorbent Dressings come in two models, Sorbact® Foam Gentle Border and Sorbact® Superabsorbent, for use with moderately or heavily exuding wounds, respectively. Both dressings come in multiple sizes, are sterile (EO), hydrophobic microbe binding, and for single use only. The dressings combine a Sorbact® wound contact layer with absorbent polyurethane foam or a superabsorbent core. The dressings are covered by a semi-permeable polyurethane film or polypropylene non-woven. A fixation border is made of silicone adhesive.

V. INDICATIONS FOR USE

Rx.: Sorbact® Foam Gentle Border is indicated for use in the management of moderately exuding partial to full thickness wounds (including clean, colonized, contaminated, or infected wounds): chronic wounds (venous and arterial ulcers, diabetic ulcers and pressure ulcers), postoperative dehisced wounds and traumatic wounds.

Rx.: Sorbact® Superabsorbent is indicated for use in the management of heavily exuding partial to full thickness wounds (including clean, colonized, contaminated, or infected wounds): chronic wounds (venous and arterial ulcers, diabetic ulcers and pressure ulcers), postoperative dehisced wounds and traumatic wounds.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Characteristic	Sorbact® Wound Dressings	Cutimed® Sorbact® Wound Dressings K143151
Intended use	Sorbact® Foam Gentle Border is indicated for use in the management of moderately exuding partial to full thickness wounds (including clean, colonized, contaminated, or infected wounds): chronic wounds (venous and arterial ulcers, diabetic ulcers and pressure ulcers), postoperative dehisced wounds and traumatic wounds. Sorbact® Superabsorbent is indicated for use in the management of heavily exuding partial to full thickness wounds (including clean, colonized, contaminated, or infected wounds): chronic wounds (venous and arterial ulcers, diabetic ulcers and pressure ulcers), postoperative dehisced wounds and traumatic wounds.	Cutimed® Sorbact® Hydroactive is indicated for use in the management of low to moderate exuding partial to full thickness wounds (including clean, colonized, contaminated, or infected wounds): chronic wounds (venous and arterial ulcers, diabetic ulcers and pressure ulcers), postoperative dehisced wounds and traumatic wounds. Cutimed® Sorbact® Hydroactive B is indicated for use in the management of low to moderate exuding partial to full thickness wounds (including clean, colonized, contaminated, or infected wounds): chronic wounds (venous and arterial ulcers, diabetic ulcers and pressure ulcers), postoperative dehisced wounds and traumatic wounds. Cutimed® Siltec® Sorbact® is indicated for use in the management of moderately to heavily exuding partial to full thickness wounds (including clean, colonized, contaminated, or infected wounds): chronic wounds (venous and arterial ulcers, diabetic ulcers and pressure ulcers), postoperative dehisced wounds and traumatic wounds.

Device Design	The Sorbact® Absorbent Dressings are designed with an acetate fabric coated with DACC (Sorbact®) in combination with an absorbent core, which absorbs and retains wound exudate. The dressings include a semi-permeable polyurethane film to allow vapor and oxygen to penetrate or water-repellent polypropylene non-woven. Sorbact® Foam Gentle Border is also designed with a silicone adhesive border for fixation.	The Cutimed® Sorbact® Wound Dressings are designed with an acetate fabric coated with DACC (Sorbact®) in combination with an absorbent core, which absorbs and locks exudate from the wound, and a transparent semi-permeable polyurethane film to allow vapor and oxygen to penetrate the film. It is also designed with an adhesive layer for fixation (except the Hydroactive dressing).
Wound Contact Material	Sorbact® fabric (acetate fabric coated with dialkyl carbamoyl chloride, DACC)	Same
Exudate Absorption Material	Polyurethane foam or polyacrylate superabsorbent particles	Hydropolymer matrix or superabsorbent polyurethane foam
Backing	Polyurethane film or polypropylene non-woven	Polyurethane film
Self-adhesive Border	Yes (for Sorbact® Foam Gentle Border)	Yes (for Cutimed® Sorbact® Hydroactive B and Cutimed® Siltec® Sorbact®)
Mechanism of Action	Used for the management of clean, colonized, contaminated, or infected wounds; rapidly absorbs and locks exudate within an absorbent core; allows water vapor to evaporate from the skin to the outside protecting the skin from maceration	Used for the management of clean, colonized, contaminated, or infected wounds; rapidly absorbs and locks exudate within an absorbent core; allows water vapor and gases to evaporate from the skin to the outside protecting the skin from maceration
Sizes	Multiple sizes	Multiple sizes
Wear Time	Up to 4 days	Up to 4 days
Biocompatible	Yes	Yes

Sterilization	Ethylene Oxide (SAL 10^{-6})	Gamma irradiation (SAL 10^{-6}) for Cutimed® Sorbact® Hydroactive and Cutimed® Sorbact® Hydroactive B; Ethylene Oxide (SAL 10^{-6}) for Cutimed® Siltec Sorbact®
Single Use	Yes	Yes
Storage Conditions	Dry and away from sunlight. For Sorbact® Superabsorbent: below 25°C	Dry, below 25°C
Shelf Life	3 years (Sorbact® Superabsorbent) 5 years (Sorbact® Foam Gentle Border	3 years

Characteristic	**Sorbact® Absorbent Dressings**	**Sorbact® Wound Dressings K063059**
Other technological characteristics: Mechanism of action	Sorbact® can bind hydrophobic microbes based on *in vitro* testing of the following strains: *S. aureus*, *S. gordonii*, *P. aeruginosa*, and *E. coli*. When the dressing is removed, microbes adhered to the dressing will be removed.	Same

VII. PERFORMANCE DATA

To verify that the device design met its functional performance and safety requirements, representative samples of the device underwent testing.

Bench testing

Performance verification testing (fluid handling tests, packaging tests)
Stability testing
Sterilization validation testing

Biocompatibility testing

The biocompatibility evaluation of the devices was conducted in accordance with the FDA *Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing"*. Testing was performed on representative samples of the devices and included the following tests:

- Cytotoxicity
- Irritation
- Sensitization

VIII. CONCLUSIONS

ABIGO Medical AB considers the Sorbact® Absorbent Dressings to be as safe, as effective, and performing as well as the predicate devices described above. This conclusion is based on the devices' similarities in intended use, design, mechanisms of action, technology, materials and performance.

Note: No clinical information has been submitted