DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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August 21, 2017

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

Re: K171225
Trade/Device Name: Sorbact Wound Dressing-Ribbon Gauze
Regulatory Class: Unclassified
Product Code: FRO
Dated: May 23, 2017
Received: May 24, 2017

Dear Deborah 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 (DICE) 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" (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 Industry and Consumer Education (DICE) 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,

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)*
K171225

Device Name
Sorbact Ribbon Gauze

Indications for Use *(Describe)*
Sorbact Ribbon Gauze is intended for use in the management of exuding partial to full thickness wounds (including clean, colonized, contaminated or infected wounds). Sorbact Ribbon Gauze is indicated for shallow cavity wounds and fistulas.

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.

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Section 6: 510(k) Summary

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Date Prepared: April 25, 2017

Trade Name: Sorbact® Wound Dressing – Ribbon Gauze

Common Name: Wound Dressing

Regulatory Class: Unclassified (Pre-amendment)

Review Panel: General & Plastic Surgery

Product Code: FRO

Predicate Device: K063059, Sorbact® Wound Dressings – Ribbon Gauze
ABIGO Medical AB

Device Description:
Sorbact® Ribbon Gauze is a sterile (gamma irradiation), single use only, hydrophobic microbe binding wound dressing. It consists of a Sorbact® wound contact layer, which allows passage of wound exudate into a secondary dressing.

Indication for Use:
Rx: Sorbact® Ribbon Gauze is intended for use in the management of exuding partial to full thickness wounds (including clean, colonized, contaminated or infected wounds). Sorbact® Ribbon Gauze is indicated for shallow cavity wounds and fistulas.

Comparison of Technological Characteristics with the Predicate Device:
The modification addressed by this 510(k) is a change to the color additive in the Sorbact® Ribbon Gauze. As the intended use, device description, wound contact material, instructions for use, mechanism of action, storage conditions, and shelf life of the modified device are the same as that of the predicate device, both devices have the same fundamental scientific technology.

Performance Data:
To verify that the device design met its functional performance and safety requirements, representative samples of the device underwent the following testing. The results of non-clinical testing demonstrate that the device met all performance requirements and that the subject device is substantially equivalent to the predicate device.

- **Extraction testing**
  - Evaluation of extractable colorants

- **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
- Intracutaneous reactivity
- Sensitization
- Systemic toxicity (acute)

Conclusion:
ABIGO Medical AB considers the Sorbact® Ribbon Gauze to be substantially equivalent to the predicate device.