August 3, 2018

Advanced Medical Solutions Ltd.
Rose Guang
QA/RA Director
Premier Park, 33 Road One, Winsford Industrial Estate
Winsford, CW7 3RT Gb

Re: K181197
Trade/Device Name: PHMB Foam Wound Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: May 2, 2018
Received: May 7, 2018

Dear Rose Guang:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181197

Device Name
PHMB Foam Wound Dressing

Indications for Use *(Describe)*
PHMB Foam Wound Dressings are indicated for use in the management of post-surgical incisions, pressure sores, venous stasis ulcers, diabetic ulcers, donor sites, abrasions , lacerations, 1st and 2nd degree burns, dermatologic disorders, other wounds inflicted by trauma and, as a secondary dressing or cover dressing for packed 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.

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

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510(k) Summary Statement

Submitted by:	Advanced Medical Solutions Ltd Premier Park 33 Road One Winsford Industrial Estate Winsford Cheshire CW7 3RT Tel: +44 1606 863500 Fax: +44 1606 863600
Contact Person:	Rose Guang
Date of Summary:	03 August 2018
Trade Name:	PHMB Foam Wound Dressing
Common Name:	PHMB Wound Dressing
Classification Name:	Dressing, Wound, Drug
Classification:	Unclassified (Pre-amendment)
Classification Code:	Product code: FRO
Predicate Device(s):	PHMB Foam Wound Dressing (K163062)
Reference Device(s):	Kendall™ AMD Antimicrobial Wound Dressing (K082296)

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Device Description:

The subject device, PHMB Foam Wound Dressing, is a polyurethane foam impregnated with Polyhexamethylene Biguanide (PHMB), an agent that protects the dressing from bacterial penetration and colonization.

The foam in the dressings has a microporous hydrophilic foam structure that absorbs wound exudate and maintains a moist wound healing environment.

Based on *in vitro* performance data, the PHMB Foam Wound Dressing provides a barrier to bacterial penetration through the dressing and the PHMB prevents colonization and proliferation of bacteria within the dressing for up to 7 days.

PHMB Foam dressing, when tested *in-vitro* has demonstrated to be effective against the following three gram positive bacteria (MRSA, MRSE, VRE), three gram negative bacteria (*Escherichia coli, Klebsiella pneumoniae, Pseudomonas aeruginosa*) and two yeast (*Candida albicans, Rhodotorula mucilaginosa*) challenge organisms within the dressing.

The device is available in Non-border (non-adhesive) and Border (adhesive) versions.

The dressing is supplied sterile in a range of sizes between 4 in^2 to 64 in^2.

Indication for Use:

PHMB Foam Wound Dressings are indicated for use in the management of post-surgical incisions, pressure sores, venous stasis ulcers, diabetic ulcers, donor sites, abrasions , lacerations, 1st and 2nd degree burns, dermatologic disorders, other wounds inflicted by trauma and, as a secondary dressing or cover dressing for packed wounds.

Substantial Equivalence:

PHMB Foam Wound Dressing has substantially equivalent intended use and labeling, identical design, materials, and performance characteristics to the predicate device PHMB Foam Wound Dressing (K163062).

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Technological characteristics:

PHMB Foam Wound Dressing is a multi-layer one piece dressing design incorporating an absorbent polyurethane foam pad containing 0.8-1.1 %w/w PHMB which is efficacious against three gram negative bacteria, three gram positive bacteria, and two yeast microorganisms within the dressing. The dressing is semi-occlusive allowing the exchange of gases such as oxygen and moisture, and has a film that provides a barrier to bacterial penetration through the dressing. The wound contact side of the dressing protects the wound bed from adhering to the dressing. PHMB Foam Wound Dressing is identical to the predicate device listed when compared to the technological characteristics such as design, materials, chemical composition, and manufacture and are supplied sterile for single use.

Performance Testing Summary:

Performance data submitted in support of this 510k included *in-vitro* and animal testing.

Performance testing included total fluid handling and peel adhesion (adhesive version only). In addition broad spectrum activity was demonstrated to be effective against the following three gram positive bacteria, three gram negative bacteria and two yeast challenge organisms within the dressing:

Methicillin-Resistant *S. aureus* (*MRSA*)
Methicillin Resistant *S. epidermidis* (*MRSE*)
Vancomycin-Resistant *E. faecalis (VRE)*
Pseudomonas aeruginosa
Escherichia coli
Klebsiella pneumoniae
Candida albicans
Rhodotorula mucilaginosa

Biological evaluation for prolonged contact (<30 days), conducted in accordance with "Use of International Standard ISO 10993-1, *Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a Risk Management process*" demonstrates that PHMB Foam Wound Dressings meet the requirements of BS EN ISO 10993-1 (Biological Evaluation of Medical Devices) and are safe.

Conclusion:

Based on the information provided within this 510(k) submission, Advanced Medical Solutions Ltd. concludes that the proposed PHMB Foam Wound Dressing is substantially equivalent to the predicate device listed and does not raise different questions of safety or effectiveness.