July 25, 2019

Advanced Medical Solutions Ltd.
Adam Gregory
Senior RA Associate
Premier Park, 33 Road One, Winsford Industrial Estate
Winsford, CW7 3RT
GB

Re: K190819
Trade/Device Name: Silicone PHMB Foam Wound Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: June 28, 2019
Received: July 1, 2019

Dear Adam Gregory:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Cynthia Chang, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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)*
K190819

Device Name
Silicone PHMB Foam Wound Dressing

Indications for Use *(Describe)*
Silicone 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.

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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:	Adam Gregory
Date of Summary:	25 July 2019
Trade Name:	Silicone 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 (K181197)

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Device Description:

The subject device, Silicone PHMB Foam Dressing, is a polyurethane foam trilaminate dressing 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 Silicone 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. Silicone PHMB Foam Wound Dressing, when tested *in-vitro* has demonstrated to be effective against the following bacteria (*MRSA*, *Streptococcus pyogenes*, *VRE*, *Escherichia coli, Klebsiella pneumoniae, Serratia marcescens*) and yeast (*Candida albicans*) challenge organisms within the dressing.

The perforated wound contact layer contains a gentle silicone adhesive that provides secure, non-irritating adhesion and supports non-traumatic removal during dressing changes.

The device is presented in a border (adhesive) version. The dressing is supplied sterile in a range of sizes between 10.24 in^2 to 64 in^2.

Indication for Use:

Silicone 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:

Silicone PHMB Foam Wound Dressing has substantially equivalent intended use, design, materials, labeling, and performance characteristics to the predicate device PHMB Foam Wound Dressing (K181197).

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Device Type	**Subject**	**Predicate**	**Substantial Equivalence**
Product Name	**Silicone PHMB Foam Wound Dressing**	**PHMB Foam Wound Dressing**	
Indications for Use			
Intended Use	Wound dressing containing PHMB designed for the management of wounds.	Wound dressing containing PHMB designed for the management of wounds.	Equivalent
Indications for Use	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 • as a secondary dressing or cover dressing for packed wounds.	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 • as a secondary dressing or cover dressing for packed wounds.	Equivalent
Single Use	Yes	Yes	Equivalent
Materials			
Construction	Polyurethane backing layer	Polyurethane backing layer	Comparison to predicate device shows no new questions of safety or effectiveness, and no change to intended use compared to predicate or reference device
	Polyurethane foam layer containing Polyhexamethylene Biguanide (PHMB)	Polyurethane foam layer containing Polyhexamethylene Biguanide (PHMB)	
	Clear polyurethane wound contact layer with silicone adhesive	Clear polyurethane wound contact layer with acrylic adhesive	
Performance			
Exudate	A high absorbency capacity for	A high absorbency capacity for	Equivalent

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Management	wound exudates and high total fluid handling	wound exudates and high total fluid handling	
Moist Environment	Maintains a moist wound healing environment	Maintains a moist wound healing environment	Equivalent
Wound Protection	Provides a barrier to bacterial penetration through the dressing	Provides a barrier to bacterial penetration through the dressing	Equivalent
Sterility	Yes, Ethylene Oxide	Yes, Gamma irradiation	Comparison to predicate device shows no new questions of safety or effectiveness, and no change to intended use compared to predicate or reference device

Technological characteristics

Silicone 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 bacteria and 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 silicone wound contact layer contains a gentle silicone adhesive that provides secure, non-irritating adhesion and supports non-traumatic removal during dressing changes. Silicone PHMB Foam Wound Dressing is equivalent 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.

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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. In addition broad spectrum activity was demonstrated to be effective against the following bacteria and yeast challenge organisms within the dressing:

Methicillin-Resistant S. aureus (MRSA)
Streptococcus pyogenes
Vancomycin-Resistant E. faecalis (VRE)
Escherichia coli
Klebsiella pneumonia
Serratia marcescens
Candida albicans

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 Silicone 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 Silicone PHMB Foam Wound Dressing is substantially equivalent to the predicate device listed.