April 5, 2023

Advanced Medical Solutions Limited
Kay McGrath
Regulatory Affairs Specialist
Premier Park, 33 Road One
Winsford Industrial Estate
Winsford, Cheshire CW7 3RT
United Kingdom

Re: K223310
Trade/Device Name: Antimicrobial Silicone PHMB Foam Wound Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: March 6, 2023
Received: March 6, 2023

Dear Kay Mcgrath:

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,

Julie A. Morabito -S

Julie Morabito, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223310

Device Name
Antimicrobial Silicone PHMB Foam Wound Dressing

Indications for Use *(Describe)*
Antimicrobial 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,
• superficial and partial thickness 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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Registered in England 2666957 VAT No. GB 636 5551 27

K223310

510(k) Summary

Submitted by:	Advanced Medical Solutions Ltd Premier Park 33 Road One Winsford Industrial Estate Winsford Cheshire CW7 3RT Tel: +44 1606 863500
Contact Person:	Kay M^{c}Grath
Date of Summary:	April 04, 2023
Trade Name:	Antimicrobial Silicone PHMB Foam Wound Dressing
Common Name:	Wound Dressing
Classification Name:	Dressing, Wound, Drug
Classification:	Unclassified (Pre-amendment)
Classification Code:	Product code: FRO
Predicate Device(s):	Silicone PHMB Foam Wound Dressing (K190819)

UK Authorised Economic Operator
Certificate No. MD 78010

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Device Description:

Antimicrobial Silicone PHMB Foam Wound 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 dressing has a microporous hydrophilic foam structure that absorbs wound exudate and maintains a moist wound healing environment.

Based on *in vitro* performance data, the Antimicrobial Silicone PHMB Foam Wound Dressing provides a barrier to bacterial penetration through the dressing and the PHMB prevents colonization and proliferation of bacteria, yeast and mold within the dressing for up to 7 days. Antimicrobial Silicone PHMB Foam Wound Dressing, when tested *in-vitro* has demonstrated to be effective against gram positive bacteria, gram negative bacteria, yeast and mold 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 (64cm) to 64 in^2 (400cm).

Indications for Use:

Antimicrobial Silicone PHMB Foam Wound Dressing is indicated for use in the management of post-surgical incisions, pressure sores, venous stasis ulcers, diabetic ulcers, donor sites, abrasions, lacerations, superficial and partial thickness burns, dermatologic disorders, other wounds inflicted by trauma and as a secondary dressing or cover dressing for packed wounds.

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Comparison of Technological Characteristics:

Antimicrobial Silicone PHMB Foam Wound Dressing is a modification of the predicate device to include updated product labelling in support of an antimicrobial product offering.

Antimicrobial Silicone PHMB Foam Wound Dressing has substantially equivalent intended use and performance characteristics, identical design, materials and manufacture process to the predicate device Silicone PHMB Foam Wound Dressing (K190819). Antimicrobial 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. Based on *in vitro* testing, the PHMB within the dressing is efficacious against gram positive bacteria, gram negative bacteria, yeast and mold. The dressing is semi-occlusive allowing the exchange of gases within the dressing 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. The following table shows the comparison of technological characteristics between the subject and predicate devices.

	Subject (modified device)	**Predicate**	**Similarities and Differences**
Product Name	**Antimicrobial Silicone PHMB Foam Wound Dressing**	**Silicone PHMB Foam Wound Dressing**	
Manufacturer	**Advanced Medical Solutions Ltd**	**Advanced Medical Solutions Ltd**	Identical
510(k)	**K223310**	**K190819**	-
Classification	Unclassified (pre-amendment)	Unclassified (pre-amendment)	Identical
Product code	FRO (Dressing, Wound, Drug)	FRO (Dressing, Wound, Drug)	Identical
Indications for use	Antimicrobial 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, superficial and partial thickness burns, dermatologic disorders, other wounds inflicted by trauma and, as a secondary dressing or cover	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	Different - Subject device includes an antimicrobial claim

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	dressing for packed wounds.	dressing for packed wounds.	
Primary Material	Polyurethane (PU) foam	Polyurethane (PU) foam	Identical
Antimicrobial agent	PHMB (0.8-1.1%w/w)	PHMB (0.8-1.1%w/w)	Identical
Sterilization method (terminal)	Ethylene oxide SAL 10^{-6}	Ethylene oxide SAL 10^{-6}	Identical
Biocompatibility	Biocompatible	Biocompatible	Identical
Storage	Store below 25°C (77°F)	Store below 25°C (77°F)	Identical
Range of available sizes	10.24 in^2 (64cm) to 64 in^2 (400cm)	10.24 in^2 (64cm) to 64 in^2 (400cm)	Identical

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Performance Testing Summary:

Microbial efficacy performance data submitted in support of this 510(k) includes *in-vitro* testing against a mold challenge organism. Testing was performed on real time aged predicate device in accordance with the well-established modified AATCC TM 100 method previously used for the predicate device.

No other performance tests were conducted for this submission. All performance data leveraged from the predicate device was submitted as part of the original 510(k) submission of the predicate, Silicone PHMB Foam Wound Dressing (K190819) and includes:

Biocompatibility

ISO 10993-1; Biological evaluation of medical devices
USP 41-NF36; <151> Pyrogenic Test

Performance testing

BS EN 13726-1; Test methods for primary wound dressings – aspects of absorbency.
BS EN 13726-2; Test methods for primary wound dressings – moisture vapour transmission rate of permeable film dressings.
BS EN 13726-3; Test methods for primary wound dressings – waterproofness.
ASTM D6282-11; Standard Test Method for 90 Degree Peel Resistance of Adhesives.
Bacterial barrier.

Distribution

ASTM D4169 – Standard Practice for Performance Testing of Shipping Containers and Systems

The subject device, Antimicrobial Silicone PHMB Foam Wound Dressing, is manufactured with the exact same materials and processes as the predicate.

Rationale for Substantial Equivalence:

The modified device, Antimicrobial Silicone PHMB Foam Wound Dressing, is identical to the predicate, Silicone PHMB Foam Wound Dressing (K190819), with regard to technology, materials, manufacture process, intended use, and target population. The only difference between the predicate and subject device is that the subject device has an antimicrobial claim, this minor modification does not raise any new questions of safety or effectiveness. Therefore, the Antimicrobial Silicone PHMB Foam Wound Dressing, is substantially equivalent to the predicate, Silicone PHMB Foam Wound Dressing (K190819).

Conclusion:

Antimicrobial Silicone PHMB Foam Wound Dressing is substantially 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. Based on the information provided within this 510(k), Advanced Medical Solutions Ltd. concludes that the proposed Antimicrobial Silicone PHMB Foam Wound Dressing is substantially equivalent to the predicate device listed, Silicone PHMB Foam Wound Dressing (K190819).