October 26, 2023

Advanced Medical Solutions Ltd.
Kay Mcgrath
RA Manager
Premier Park, 33 Road One, Winsford Industrial Estate
Winsford, Cheshire CW7 3RT
United Kingdom

Re: K213473
Trade/Device Name: Antimicrobial Gelling Fiber Dressing with PHMB
Regulatory Class: Unclassified
Product Code: FRO
Dated: June 15, 2023
Received: June 15, 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

David Krause -S

David Krause, Ph.D.
Assistant Director
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K213473

Device Name
Antimicrobial Gelling Fiber Dressing with PHMB

Indications for Use *(Describe)*

Prescription Use:
Under the supervision of a healthcare professional, the Antimicrobial Gelling Fiber Dressing with PHMB is indicated for the management of:
• Post-surgical incisions
• Pressure ulcers
• Diabetic ulcers
• Venous stasis ulcers
• Donor sites
• Abrasions
• Lacerations
• Superficial and Partial thickness burns
• Dermatologic disorders
• Other wounds inflicted by trauma

Over-the-Counter Use:
The Antimicrobial Gelling Fiber Dressing with PHMB may be used for the management of:
• Minor abrasions
• Minor lacerations
• Minor cuts
• Minor scalds and bums

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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Traditional 510(k) Summary Statement

Manufacturer:	Advanced Medical Solutions Ltd Premier Park, 33 Road One, Winsford Industrial Estate Winsford, Cheshire UK CW7 3RT Tel: +44 1606 863500 Fax: +44 1606 863600
Contact:	Kay McGrath Regulatory Affairs Manager Advanced Medical Solutions Tel: +44 7791 188193 kay.mcgrath@admedsol.com
Date of Summary:	August 22, 2023
Trade Name:	Antimicrobial Gelling Fiber Dressing with PHMB
Classification Name:	Dressing, Wound, Drug
Classification:	Unclassified
Product Code:	FRO
Predicate Device(s):	Primary Predicate: AMS PHMB Foam Wound Dressing (K181197) Secondary Predicate: Aquacel Ag^{+} Extra (K173675) [Branded as Aquacel Advantage Ag]

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Device Description:

Antimicrobial Gelling Fiber Dressing with PHMB, is a sterile, non-woven pad or rope composed of carboxymethylcellulose (CMC) fibers, Polyhexamethylene Biguanide (PHMB), Ethylenediaminetetraacetic acid (EDTA), and a reinforcement layer (nylon) for intact removal. The dressing is soft, conformable, and highly absorbent, making it ideal for use with moderate to heavily exuding chronic and acute wounds. As wound exudate containing microorganisms is absorbed and trapped within the dressing, a gel is formed that conforms to the wound bed and anatomical contours, and aids in maintaining a moist wound environment and removing non-viable tissue and slough (autolytic debridement). This is conducive to the natural healing process.

The dressing contains an active ingredient, PHMB. Based on *in vitro* performance data, the Antimicrobial Gelling Fiber Dressing with PHMB effectively reduces microbial colonization within the dressing for up to 7 days.

The device is presented in a range of both flat/pad (160 g/m^2 and 200 g/m^2) and rope (160 g/m^2) dressings. The dressings are manufactured consistently using the same raw materials, the same manufacturing lines, follow a similar manufacturing process and utilize the same sterilization route. The sterile dressings are supplied in a range of sizes between 4in^2 (25cm^2) to 96in^2 (600cm^2).

Indications for Use:

Prescription Use:
Under the supervision of a healthcare professional, the Antimicrobial Gelling Fiber Dressing with PHMB is indicated for use in the management of: Post-surgical incisions, Pressure ulcers, Diabetic ulcers, Venous stasis ulcers, Donor sites, Abrasions, Lacerations, Superficial and Partial thickness burns, Dermatological disorders, Other wounds inflicted by trauma.

Over-the-Counter Use:
The Antimicrobial Gelling Fiber Dressing with PHMB may be used for the management of: Minor Abrasions, Minor Lacerations, Minor cuts, Minor scalds and burns.

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Comparison of Technological Characteristics:

Antimicrobial Gelling Fiber Dressing with PHMB is a multi-layer one piece dressing design incorporating an absorbent non-woven pad or rope composed of carboxymethylcellulose (CMC) fibers, containing 0.3 – 0.9%w/w PHMB. Based on *in vitro* testing, the PHMB within the dressing has been shown to be effective against gram-positive and gram-negative bacteria, mold, and yeast microorganisms. The dressing is designed to minimize the risk of maceration and damage to newly formed tissue. The dressing, when gelled with exudate is non-adherent to the wound bed and can be easily removed. The Antimicrobial Gelling Fiber Dressing with PHMB can be used under compression. The following table shows a comparison of technological characteristics between the subject device and the predicate and reference devices.

	Subject	**Primary Predicate**	**Secondary Predicate**
Product Name	**Antimicrobial Gelling Fiber Dressing with PHMB**	**PHMB Foam Wound Dressing**	**Aquacel Ag⁺ Extra**
Manufacturer	**Advanced Medical Solutions Ltd**	**Advanced Medical Solutions Ltd**	**Convatec**
510(k)	**K213473**	**K181197**	**K173675**
Classification	Unclassified (pre-amendment)	Unclassified (pre-amendment)	Unclassified (pre-amendment)
Product code	FRO (Dressing, Wound, Drug)	FRO (Dressing, Wound, Drug)	FRO (Dressing, Wound, Drug)
Indications for use	**Prescription Use**: Under the supervision of a healthcare professional, the Antimicrobial Gelling Fiber Dressing with PHMB is indicated for use in the management of post-surgical incisions, pressure ulcers, venous stasis ulcers, diabetic ulcers, donor sites, abrasions, lacerations, superficial and partial thickness burns, dermatologic disorders, other wounds inflicted by trauma.	**Prescription 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.	**Prescription Use**: Under the supervision of a healthcare professional: AQUACEL Ag+ EXTRA Enhanced Hydrofiber Dressing with Silver and Strengthening Fiber may be used for the management of: Wounds as an effective barrier to bacterial penetration of the dressing as this may help reduce infection, Partial thickness (second degree) burns, Diabetic foot ulcers, leg ulcers, (venous stasis ulcers, arterial ulcers, and leg ulcers of mixed etiology) and pressure ulcers/sores (partial & full thickness), Surgical wounds left to heal by secondary intention such as dehisced surgical incisions, Surgical wounds that heal by primary intent such as dermatological and surgical incisions (e.g., orthopedic and vascular), Traumatic

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	Over-the-Counter Use: The Antimicrobial Gelling Fiber Dressing with PHMB may be used for the management of minor abrasions, minor lacerations, minor cuts, minor scalds and burns		wounds, Wounds that are prone to bleeding, such as wounds that have been mechanically or surgically debrided and donor sites, Oncology wounds with exudate, such as fungoides-cutaneous tumors, fungating carcinoma, cutaneous metastasis, Kaposi's sarcoma, and angiosarcoma, Management of painful wounds, Infected wounds. **Over-the-Counter Use**: The AQUACEL Ag+ EXTRA Enhanced Hydrofiber Dressing with Silver and Strengthening Fiber may be used for the management of: Abrasions, Lacerations, Minor cuts, Minor scalds and burns
Primary Material	Carboxymethylcellulose (CMC) non-woven fiber	Polyurethane (PU) foam	Sodium carboxymethylcellulose (CMC) non-woven
Antimicrobial agent	PHMB	PHMB	Silver
Sterility	Gamma irradiation SAL 10^{-6}	Ethylene oxide SAL 10^{-6}	Gamma irradiation SAL 10^{-6}
Biocompatibility	Biocompatible	Biocompatible	Biocompatible
Storage	Store below 25°C (77°F)	Store below 25°C (77°F)	10-25°C / 50-77°F

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Performance Testing Summary:

Performance testing included total fluid handling (including absorbency and shrinkage studies), physical testing to assess the wet, dry, and bond strength, stability testing, and package integrity testing. In addition, broad spectrum activity was demonstrated to be effective against the following three gram-positive bacteria, three gram-negative bacteria, one yeast, and one mold challenge organisms within the dressing:

Methicillin-Resistant *S. aureus* (MRSA), Methicillin Resistant *S. epidermidis* (MRSE), Vancomycin-Resistant *E. faecalis* (VRE), *Pseudomonas aeruginosa, Enterobacter Cloacae, Klebsiella pneumonia, Cryptococcus neoformans,* and *Acremonium strictum*

Biocompatibility

ISO 10993-1; Biological evaluation of medical devices

Performance testing

BS EN 13726-1; Test methods for primary wound dressings – aspects of absorbency.
ATCC TM 100; Test Method for Antibacterial Finishes on Textile Materials (modified)

Distribution

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

Rationale for Substantial Equivalence:

Antimicrobial Gelling Fiber Dressing with PHMB has substantially equivalent intended use, target population, active antimicrobial agent, biological characteristics, and performance characteristics to the predicate device, PHMB Foam Wound Dressing (AMS Ltd, K181197).

Conclusion:

Based on the information provided within this Traditional 510(k) submission, Advanced Medical Solutions Ltd. concludes that the proposed Antimicrobial Gelling Fiber Dressing with PHMB is substantially equivalent to the predicate device listed.