May 12, 2021

Advanced Medical Solutions Ltd.
Kay McGrath
Regulatory Affairs Manager
Premier Park, 33, Winsford Industrial Estate
Winsford, Cheshire CW7 3RT
United Kingdom

Re: K210974
Trade/Device Name: High Performance Antimicrobial Gelling Fiber with Silver
Regulatory Class: Unclassified
Product Code: FRO
Dated: March 30, 2021
Received: April 1, 2021

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,

Lixin Liu, Ph.D.
Acting 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)*
K210974

Device Name
High Performance Antimicrobial Gelling Fiber with Silver

Indications for Use *(Describe)*
Under the supervision of a healthcare professional, High Performance Antimicrobial Gelling Fiber with Silver can be used in the management of moderate to heavily exuding chronic and acute wounds. The antimicrobial dressing is indicated for use on the following wounds;

- Pressure ulcers (partial and full thickness)
- Leg ulcers (venous stasis ulcers, arterial ulcers and leg ulcers of mixed etiology)
- Diabetic foot ulcers
- Surgical wounds that heal by primary intent such as dermatological and surgical incisions
- Surgical wounds left to heal by secondary intention such as dehisced surgical incisions and donor sites
- Traumatic 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Advanced Medical Solutions Limited
Premier Park, 33 Road One
Winsford Industrial Estate
Cheshire. CW7 3RT. UK

Advanced Medical Solutions Ltd

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:	May 04, 2021
Trade Name:	High Performance Antimicrobial Gelling Fiber with Silver
Common Name:	Wound Dressing
Classification Name:	Dressing, Wound, Drug
Classification:	Unclassified (Pre-amendment)
Classification Code:	Product code: FRO
Predicate Device(s):	Silver High Performance Dressing (K183645)

Advanced Medical Solutions Limited
Premier Park, 33 Road One
Winsford Industrial Estate
Cheshire. CW7 3RT. UK

Advanced Medical Solutions Ltd

Device Description:

High Performance Antimicrobial Gelling Fiber with Silver is an antimicrobial, absorbent gelling fiber dressing comprising of a non-woven pad or ribbon containing ionic silver, with a reinforcement layer to allow intact application and removal of the dressing. The dressing is sterile, soft and conformable to anatomical contours.

High Performance Antimicrobial Gelling Fiber with Silver manages exudate in moderate to heavily exuding wounds and helps create a favorable environment for moist wound healing. The highly absorbent dressing absorbs exudate from the wound to form a soft gel that intimately conforms to the wound bed and aids in maintaining a moist wound environment, which is conducive to the wound healing environment and aids autolytic debridement (removal of non-viable tissue). The dressing is designed to minimize the risk of maceration and damage to newly formed tissue. High Performance Antimicrobial Gelling Fiber with Silver can be used under compression.

High Performance Antimicrobial Gelling Fiber with Silver contains ionic silver, and effectively manages and suppresses colonization and proliferation of micro-organisms within the dressing for up to 7 days.

High Performance Antimicrobial Gelling Fiber with Silver, when tested *in vitro*, has been shown to be effective against gram positive bacteria, gram negative bacteria, yeast and mold challenge organisms within the dressing.

The dressings are supplied sterile (gamma irradiation) in a range of sizes, ranging in area from 28cm^2 (4.34 in^2) to 650cm^2 (100.75 in^2).

High Performance Antimicrobial Gelling Fiber with Silver is a modification of the predicate device to include updated product labelling in support of an antimicrobial product offering.

Indications for Use:

Under the supervision of a healthcare professional, High Performance Antimicrobial Gelling Fiber with Silver can be used in the management of moderate to heavily exuding chronic and acute wounds. The antimicrobial dressing is indicated for use on the following wounds:

Pressure ulcers (partial and full thickness)
Leg ulcers (venous stasis ulcers, arterial ulcers and leg ulcers of mixed etiology)
Diabetic foot ulcers

Advanced Medical Solutions Limited
Premier Park, 33 Road One
Winsford Industrial Estate
Cheshire. CW7 3RT. UK

Advanced Medical Solutions Ltd

	Surgical wounds that heal by primary intent such as dermatological and surgical incisions Surgical wounds left to heal by secondary intention such as dehisced surgical incisions and donor sites Traumatic wounds
Substantial Equivalence:	High Performance Antimicrobial Gelling Fiber with Silver has substantially equivalent intended use and performance characteristics, identical design, materials and manufacture process to the predicate device Silver High Performance Dressing (K183645).
Technological characteristics:	High Performance Antimicrobial Gelling Fiber with Silver is a one piece non-woven dressing composed of fibers containing ionic silver, with a reinforcement layer to allow intact application and removal of the dressing. Based on *in vitro* testing, the silver within the dressing is efficacious against gram positive bacteria, gram negative bacteria, yeast and mold. The dressing is absorbent, soft and conformable to the wound bed and anatomical contours.
Performance Testing Summary:	Performance data submitted in support of this 510(k) includes *in-vitro* testing against a mold challenge organism. No other performance testing or biocompatibility evaluation were conducted for this submission. All performance data was submitted as part of the original 510(k) submission for the predicate, Silver High Performance Dressing (K183645). The subject device, High Performance Antimicrobial Gelling Fiber with Silver, is manufactured with the exact same materials and processes as the predicate.
Conclusion:	Based on the information provided within this 510(k) submission, Advanced Medical Solutions Ltd. concludes that the proposed High Performance Antimicrobial Gelling Fiber with Silver is substantially equivalent to the predicate device listed, Silver High Performance Dressing (K183645).