May 29, 2019

Advanced Medical Solutions Ltd.
Amy Turner
Senior Regulatory Affairs Associate
Premier Park, 33, Winsford Industrial Estate
Winsford, Cheshire
CW7 3RT United Kingdom

Re: K183645
Trade/Device Name: Silver High Performance Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: December 20, 2018
Received: December 26, 2018

Dear Amy Turner:

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,

For David Krause
Acting Division 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)*
K183645

Device Name
Silver High Performance Dressing

Indications for Use *(Describe)*

Under the supervision of a healthcare professional, Silver High Performance Dressing can be used in the management of moderate to heavily exuding chronic and acute wounds. The 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.

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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 Fax: +44 1606 863600
Contact Person:	Amy Turner
Date of Summary:	29 May 2019
Trade Name:	Silver High Performance Dressing
Common Name:	Wound Dressing
Classification Name:	Dressing, Wound, Drug
Classification:	Unclassified (Pre-amendment)
Classification Code:	Product code: FRO
Predicate Device(s):	AQUACEL® Ag Hydrofiber Dressing (K080383)

K183645

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Device Description:

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

Silver High Performance Dressing 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. Silver High Performance Dressing can be used under compression.

Silver High Performance Dressing contains ionic silver, and effectively manages and suppresses colonization and proliferation of bacteria and yeast within the dressing for up to 7 days.

Silver High Performance Dressing , when tested in vitro, has been shown to be effective against the following four gram positive bacteria (*Vancomycin- resistant enterococcus (VRE), Streptococcus mutans and Staphylococcus aureus and Methicillin - resistant staphylococcus epidermidis (MRSE)*), four gram negative bacteria (*Enterobacter cloacae, Klebsiella pneumonia, Serratia marcescens and Escherichia coli (E. coli)*), and yeast (*Candida albicans*) 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).

Indications for Use:

Under the supervision of a healthcare professional, Silver High Performance Dressing can be used in the management of moderate to heavily exuding chronic and acute wounds. The 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

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	Traumatic wounds
Substantial Equivalence:	Silver High Performance Dressing has substantially equivalent intended use, design, materials, labeling, and performance characteristics to the predicate device AQUACEL® Ag Hydrofiber Dressing (K080383).
Technological characteristics:	Silver High Performance Dressing 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 four gram positive bacteria, four gram negative bacteria, and a yeast. 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* and animal testing. Performance testing includes absorbency, wet integrity, lateral wicking, conformability, wet tensile strength and dry tensile strength. Silver High Performance Dressing , when tested in vitro, has been shown to be effective against the following four gram positive bacteria, four gram negative bacteria and one yeast organisms: *Vancomycin- resistant enterococcus (VRE)* *Streptococcus mutans* *Staphylococcus aureus* *Methicillin - resistant staphylococcus epidermidis (MRSE)* *Enterobacter cloacae* *Klebsiella pneumoniae* *Serratia marcescens* *Escherichia coli (E. coli)* *Candida albicans* The results of performance testing demonstrate that Silver High Performance Dressings are substantially equivalent to the predicate, AQUACEL® Ag Hydrofiber Dressing (K080383). Biocompatibility evaluation, 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 Silver High Performance Dressings meet the requirements of BS EN ISO 10993-1 (Biological Evaluation of Medical Devices) with satisfactory results except for the *in vitro* cytotoxicity study.

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A pre-clinical GLP study was performed to evaluate the local tissue effects of Silver High Performance Dressing and whether its *in vitro* cytotoxic effect may delay wound healing following repeated application to excisional full thickness dermal wounds in a porcine model. Tissues were evaluated by macroscopic and histopathological observations until robust tissue response diminished and complete re-epithelisation occurred; this study demonstrated that there were no biologically relevant differences between the test subjects (Silver High Performance Dressing, AQUACEL® Ag Hydrofiber Dressing and a Negative Control) in terms of wound healing performance characteristics and local tolerance after wound creation.

Conclusion: Based on the information provided within this 510(k) submission, Advanced Medical Solutions Ltd. concludes that the proposed Silver High Performance Dressing is substantially equivalent to the predicate device listed, Aquacel Ag Hydrofiber Dressing.