August 7, 2018

Advanced Medical Solutions Ltd.
Rose Guang
QA/RA Director
Premier Park, 33 Road One, Winsford Industrial Estate
Winsford, CW7 3RT Gb

Re: K180634
Trade/Device Name: Surgical Silver Post Operative Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: June 25, 2018
Received: July 2, 2018

Dear Rose Guang:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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)*
K180634

Device Name
Surgical Silver Post Operative Dressing

Indications for Use *(Describe)*
Under the supervision of a healthcare professional Surgical Silver Post Operative Dressing may be used in the management of post operative surgical wounds healing by primary intent, and as an effective barrier to bacterial penetration.

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

Advanced Medical Solutions Ltd

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:	Rose Guang
Date of Summary:	07 August 2018
Trade Name:	Surgical Silver Post Operative Dressing
Common Name:	Surgical Cover Dressing
Classification Name:	Dressing, Wound, Drug
Classification:	Unclassified (Pre-amendment)
Classification Code:	Product code: FRO
Predicate Device(s):	AQUACEL® Ag Surgical dressings (K091034)

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

Device Description:

The subject device, Surgical Silver Post Operative dressing, is a sterile dressing comprising of an absorbent non woven pad containing an ionic silver. This centered silver pad is secured between two layers of hydrocolloid; the outer hydrocolloid layer incorporates a breathable waterproof film. The inner layer of hydrocolloid forms a windowed self adhesive skin contact layer, which adheres to healthy skin, minimizes trauma on removal and assists in minimizing leakage. As wound fluid is absorbed the dressing forms a gel, this helps maintain a moist environment. A moist wound environment has been shown to be conducive for wound healing. The non-woven pad gelling properties allow intact removal without damage to the closure system e.g. sutures.

Based on *in vitro* performance data, the Surgical Silver Post Operative dressing provides a barrier to bacterial penetration through the dressing and the silver component prevents colonization and proliferation of bacteria within the dressing for up to 7 days.

Surgical Silver Post Operative dressings, when tested *in-vitro* have been demonstrated to be efficacious, achieving ≥4 log reduction within the dressing including multiple re-inoculations against three gram positive (MRSA, MRSE, VRE) bacteria, three gram negative bacteria (*Escherichia coli, Klebsiella pneumonia, Pseudomona areuginosa*) and yeast (*Candida albicans)* challenge organisms.

The dressings are supplied sterile (gamma irradiation) in a range of sizes between 14 in^2 to 49 in^2.

Indication for Use:

Under the supervision of a healthcare professional Surgical Silver Post Operative Dressing may be used in the management of post operative surgical wounds healing by primary intent, and as an effective barrier to bacterial penetration.

Substantial Equivalence:

Surgical Silver Post Operative Dressing has substantially equivalent intended use, design, materials, labeling, and performance characteristics to the predicate device AQUACEL® Ag Surgical dressings (K091034).

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

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Technological characteristics:

Surgical Silver Post Operative Dressing is a one piece dressing design incorporating a central silver-containing absorbent pad which is efficacious within the dressing against three gram positive and 3 gram negative bacteria, and a yeast. Two skin friendly layers of hydrocolloid secure the central silver pad in place and provide a bacterial barrier. The inner of the two hydrocolloid layers provides adhesion to the peri-wound area, securing the dressing in place.

Performance Testing Summary:

Performance data submitted in support of this 510(k) included *in-vitro* and animal testing.

Performance testing included total fluid handling, absorbency over 7 days, peel adhesion, and water and bacterial barrier.

Surgical Silver Post Operative dressings, when tested *in-vitro* have been demonstrated to be efficacious, achieving ≥4 log reduction within the dressing including multiple re-inoculations against the following 3 gram negative bacteria, 3 gram positive bacteria and a yeast organisms:

Methicillin-Resistant *S. aureus* (*MRSA*)
Methicillin Resistant *S. epidermidis* (*MRSE*)
Vancomycin-Resistant *E. faecalis (VRE)*
Pseudomonas areuginosa
Escherichia coli
Klebsiella pneumonia
Candida albicans

The results of performance testing demonstrate that Surgical Silver Post Operative Dressings are substantially equivalent to the predicate, AQUACEL® Ag Surgical dressings (K091034).

A non-clinical GLP study was performed to evaluate the local tissue effects of Surgical Silver Post Operative Dressing on wound healing following repeated application to incisional full thickness dermal wounds in a porcine model. Tissues were evaluated by macroscopic and histopathological observations until robust tissue response and complete re-epithelisation occurred; this study demonstrated that there were no biologically relevant differences amongst the test subjects (Surgical Silver Post Operative Dressing, AQUACEL® Ag Surgical dressing and a Negative Control) in terms of wound healing

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performance characteristics and local tolerance after wound creation.

Biological 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 Surgical Silver Post Operative Dressings meet the requirements of BS EN ISO 10993-1 (Biological Evaluation of Medical Devices) and is safe.
The following end points were assessed: Cytotoxicity, Irritation, Sensitization, Acute systemic toxicity, Material Mediated Pyrogenicity, Implantation, and Sub-acute/sub-chronic toxicity.

Conclusion:

Based on the information provided within this 510(k) submission, Advanced Medical Solutions Ltd. concludes that the proposed Surgical Silver Post Operative Dressing is substantially equivalent to the predicate device listed and does not raise different questions of safety or effectiveness compared to the predicate.