

MAR 14 2011

**Section 6 – Traditional 510(k) Notification: -Summary**

This Special 510(k) Device Modification is to provide substantial equivalence for the Advanced Medical Solutions Limited's Silver Antimicrobial Wound Gel, which is substantially equivalent to currently marketed devices intended for wound care. The Silver Antimicrobial Wound Gel was previously cleared under 510(k) # K073197. The submission was made by Advanced Medical Solutions Limited.

**Submitted by:-** Advanced Medical Solutions Limited  
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**Date prepared:-** 9<sup>th</sup> February 2011

**Common Name:-** Silver Antimicrobial Wound Gel

**Trade Names:-** Not yet defined

**Classification Name:-** Dressing, wound, drug

**Classification:-** Unclassified

**Product Code:-** FRO

**Legally marketed device(s) for substantial equivalence comparison:-**

Advanced Medical Solutions Limited's Silver Antimicrobial Wound Gel, 510(k) # K073197.

**Device Description:-**

Silver Antimicrobial Wound Gel is an opaque, amorphous hydrogel containing a high (>80%) water content and hydrophilic polymer chains. This formulation increases the moisture within the wound through water donation which makes the gel effective in assisting the debridement and desloughing process in dry necrotic wounds, whilst maintaining a moist wound environment for optimal wound healing.

Silver Antimicrobial Wound Gel contains an antimicrobial silver compound (silver carbonate) that is an effective barrier to bacterial penetration by inhibiting the growth of broad spectrum of microorganisms which come into contact with the gel.

Silver Antimicrobial Wound Gel is available in various sizes, and is supplied in aluminium tubes fitted with screw caps. The tubes will be packed in a cardboard dispenser box, with a product insert.

**Indications for use:-**

Silver Antimicrobial Wound Gel is indicated under the medical supervision of a healthcare professional for the management of dry to moderate exuding partial and full thickness wounds such as:

- Pressure ulcers
- Leg ulcers
- Diabetic ulcers
- Graft and donor sites
- Post-operative surgical wounds
- Trauma wounds (dermal lesions, trauma injuries or incisions)
- 1<sup>st</sup> and 2<sup>nd</sup> degree burns
- Abrasions and lacerations

**Contraindication and Precautions:-**

**Contraindication:** Silver Antimicrobial Wound Gel should not be used on patients with a known sensitivity to Silver or Propylene glycol.

**Caution:** Frequent or prolonged use of this preparation may result in permanent discoloration of skin and mucous membranes.

**Caution:** Federal [US] Law restricts this device to sale by or on the order of a physician [or properly licensed practitioner].

**Manufacturing:-**

Silver Antimicrobial Wound Gel will be manufactured according to the product specification and under good manufacturing practices (GMP). A risk analysis has been performed to identify possible failure mode during manufacturing. Manufacturing controls have been developed and implemented to address the identified risk factors based on the criticality of the failure mode. Advanced Medical Solutions Ltd meets all the established specifications prior to release to ensure the device is safe, effective and correctly labelled for its intended use.

**In-vitro Testing:-**

The antimicrobial barrier activities of the Silver Antimicrobial Wound Gel have been established by a seven day log reduction evaluation test and preservative efficacy test in accordance with the requirements of USP 33 <51> (Antimicrobial Effectiveness Testing) and European Pharmacopoeia Edition 6.6 section 5.1.3.

In-vitro testing has shown that Silver Antimicrobial Wound Gel is effective against the following broad spectrum of microorganisms; *Staphylococcus aureus*, including MRSA, *Staphylococcus epidermidis*, including MRSE, *Streptococcus pyogenes*, *Pseudomonas aeruginosa*, *Escherichia coli* and fungi such as *Candida albicans* and *Aspergillus brasiliensis* (formerly known as *Aspergillus niger*) when they come into contact with the gel. The clinical implications of the in-vitro findings are unknown.

The biocompatibility of the Advanced Medical Solutions Ltd Silver Antimicrobial Wound Gel has been demonstrated to be in compliance with the requirements of BS EN ISO 10993-1 (Biological Evaluation of Medical Devices).

**In-vivo Testing:-**

Product performance has been established using an *in-vivo* porcine study. The study assessed the dressing performance and compared the Silver Antimicrobial Wound Gel to that of a commercially available equivalent Hydrogel, manufactured by Advanced Medical Solutions which has a similar formulation to the Silver Antimicrobial Wound Gel but contains no silver compound (silver carbonate), and a "Wet to Dry" gauze dressing.

The report findings showed that the rate of wound closure in receipt of Silver Antimicrobial Wound Gel showed no statistically significant differences when compared to the Hydrogel and "Wet to Dry" gauze treatment.

Wound site adherence, though significant in "Wet to Dry" gauze treated wounds, was not detected for the Silver Antimicrobial Wound Gel or Hydrogel at any point in the study – a reflection of the gel structure of these two devices. The surface of wounds in receipt of Silver Antimicrobial Wound Gel was found to include device debris in the form of dark-coloured granules at the day 2 & 4 assessment points; however such granules were not apparent at later time points.

Peri-wound inflammation/erythema was less frequently observed and less severe in Silver Antimicrobial Wound Gel and Hydrogel treated wounds than in similar control "Wet to Dry gauze" treated wounds. No adverse effects were noted following the use of either of the Silver Antimicrobial Wound Gel or the Hydrogel "dressings" investigated.

**Statement of Substantial Equivalence:-**

The indication for use, performance testing and antimicrobial activity for the modified Silver Antimicrobial Wound Gel is substantially equivalent to Advanced Medical Solutions Limited's Silver Antimicrobial Wound Gel, 510(k) # K073197. The biocompatibility, *in-vivo* study and performance testing for the Silver Antimicrobial Wound Gel has demonstrated that the device is safe and effective for the indications of use.



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Advanced Medical Solutions Limited  
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MAR 14 2011

Re: K110458

Trade/Device Name: Silver Antimicrobial Wound Gel  
Regulatory Class: Unclassified  
Product Code: FRO  
Dated: March 15, 2011  
Received: March 18, 2011

Dear Ms. Ryan:

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. 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

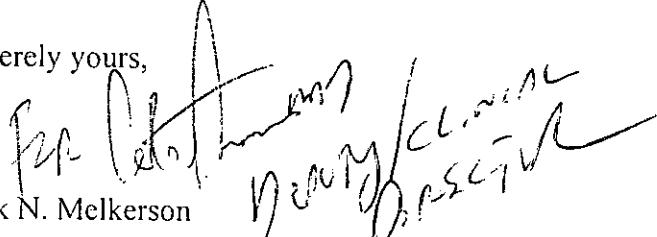
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CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

  
Mark N. Melkerson  
Director  
Division of Surgical, Orthopedic  
and Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

### Indications for Use

510(k) Number (if known): K110458

Device Name: Silver Antimicrobial Wound Gel

Indications for Use:

Silver Antimicrobial Wound Gel is indicated under the medical supervision of a healthcare professional for the management of dry to moderate exuding partial to full thickness wounds, such as:

- Pressure Ulcers
- Leg Ulcers
- Diabetic Ulcers
- Graft and donor sites
- Post-operative surgical wounds
- Trauma wounds (dermal lesions, trauma injuries or incisions)
- 1<sup>st</sup> and 2<sup>nd</sup> degree burns
- Abrasions and lacerations

Prescription Use  X  AND/OR Over-The-Counter Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krueger  
(Division Sign-Off)

Division of Surgical, Orthopedic,  
and Restorative Devices

510(k) Number K110458