AUG - 5 2004

K041316

1/2

SECTION 5

510(k) SUMMARY

This 510(k) is to provide notification of substantial equivalence for Advanced Medical Solutions Ltd's Silver Alginate II Dressing, which is substantially equivalent to currently marketed devices intended for wound care.

Submitted by: Advanced Medical Solutions Ltd.,
Road Three,
Winsford Industrial Estate,
Winsford,
Cheshire,
CW7 3PD,
England

Contact: Mr. John Greenham
Regulatory Affairs Manager

Telephone: 44 (0)1606 545569

Fax: 44 (0)1606 863600

e-mail: john.greenham@admedsol.com

Date prepared: 19th July 2004

Classification: There is currently no classification for wound and burn dressings

Trade name: Not yet defined [*Antimicrobial Alginate Dressing*]

Common name: Silver Alginate II Dressing

Predicate devices:

K002896	Acticoat® Calcium Alginate Dressing
K013814	Absorbent Antimicrobial Wound Dressing

Indications for use: Advanced Medical Solutions Ltd's Silver Alginate II Dressing is indicated for the management of moderate to heavily exuding partial to full thickness wounds, including, post-operative wounds, trauma wounds, leg ulcers, pressure ulcers, diabetic ulcers, graft and donor sites

Product Description:

The dressing is a sterile, non-woven pad composed of a high G (guluronic acid) calcium alginate, carboxymethylcellulose (CMC) and ionic silver, which absorbs wound exudate and releases silver ions in the presence of wound fluid. As wound exudate is absorbed, the alginate forms a gel, which assists in maintaining a moist environment for optimal wound healing, and allows intact removal.

The silver ions protect the dressing from a broad spectrum of microorganisms over a period of up to four (4) days, based on in vitro laboratory testing. Odour reduction results from the antibacterial effect in the dressing.

The dressing is an effective barrier to penetration by microorganisms.

The dressing has a off-white appearance, and is available in various sizes (5cm x 5cm, 10cm x 10cm, 15cm x 15cm, 10cm x 20cm flat dressings; 2.7cm x 30cm, and 3cm x 44cm flat rope dressings; and 30cm x 2g rope dressings). The flat dressings are packaged in pouches, and the flat rope and rope dressings are packaged in a blister pack.

Testing:

The biocompatibility of Advanced Medical Solutions Ltd's Silver Alginate II Dressing has been demonstrated in accordance with BS EN ISO 10993-1 requirements. Additional in vitro testing has demonstrated that the key performance characteristics of the dressing are substantially equivalent to the predicate devices.

Statement of substantial equivalence:

The Silver Alginate II Dressing is a non-woven calcium alginate dressing which is substantially equivalent in construction and/or performance to both the Acticoat® Calcium Alginate Dressing and the Absorbent Antimicrobial Wound Dressing predicate devices. Comparable absorbency, silver release profile and antimicrobial activity have been demonstrated.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 5 2004

Mr. John Greenham
Regulatory Affairs Manager
Advanced Medical Solutions, Ltd.
Road Three, Winsford Industrial Estate,
Winsford,
Cheshire, CW7 3PD U.K.

Re: K041316
Trade/Device Name: Silver Alginate II Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: May 11, 2004
Received: May 17, 2004

Dear Mr. Greenham:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K041316**

Device Name: **Silver Alginate II Dressing**

Indications For Use:

The Silver Alginate II Dressing is indicated for the management of moderate to heavily exuding partial to full thickness wounds, including:

- Post-operative wounds
- Trauma wounds
- Leg Ulcers
- Pressure Ulcers
- Diabetic Ulcers
- Graft and donor sites

Silver Alginate II Dressing is indicated for external use only

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K041316