SECTION 11.

510(k) SUMMARY.

JUN 3 0 2003

General information.

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

Submitted by:	Advanced Medical Solutions Ltd., Road Three, Winsford Industrial Estate, Winsford, Cheshire, CW7 3PD, England
Contact:	Mr. John Green Quality Assurance and Regulatory Affairs Manager
Telephone:	44 (0)1606 545612
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Date prepared:	12th December 2002
Classification: dressings	There is currently no classification for wound and burn
Trade name:	Antimicrobial Alginate Dressing
Common name:	Alginate Dressing
Predicate device:	K002896 Acticoat Calcium Alginate Dressing
Indications for use:	Advanced Medical Solutions Ltd's Antimicrobial Alginate Dressing is an effective barrier to bacterial penetration. The barrier functions of the dressing may help reduce infection in moderate to heavily exuding partial and full-thickness wounds including: pressure ulcers, venous ulcers, diabetic ulcers, donor sites, traumatic and surgical wounds.

Product description: Advanced Medical Solutions Ltd's Antimicrobial Alginate Dressing is a sterile, non-woven pad composed of a high G (guluronic acid) alginate, carboxymethylcellulose (CMC) and silver coated nylon fibres. The sustained release of silver creates a favourable environment by protecting the dressing from bacterial contamination. The dressing absorbs exudate, maintains a moist wound healing environment and allows intact removal.

The dressing has a light grey appearance, and is available in various sizes (5cm x 5cm, 11cm x 11cm, 10cm x 20cm flat dressings and 2.5cm x 30.5cm rope). The flat dressings are packaged in pouches, and the rope is packaged in a blister pack.

Testing: The biocompatibility of Advanced Medical Solutions Ltd's Antimicrobial Alginate Dressing has been demonstrated in accordance with BSENISO 10993-1. Additional *in vitro* testing has demonstrated that the performance characteristics of the dressing are substantially equivalent to the predicate device.

Statement of substantial equivalence:

The materials from which the devices are manufactured are similar, and both devices are produced from calcium alginate and incorporate silver.

The Antimicrobial Alginate Dressing and the predicate device have the same intended use, and have almost identical indications for use, (e.g. pressure ulcers, venous ulcers, diabetic ulcers, traumatic and surgical wounds).

The Antimicrobial Alginate Dressing and the predicate device consist of absorbent materials, are provided sterile to the user, and both devices provide a sustained release of broad spectrum ionic silver, when activated by moisture, to provide an antimicrobial effect to protect the dressing from bacterial contamination for up to 3 days. Both devices provide an effective barrier to bacterial penetration. The barrier functions of both dressings may help reduce infection in moderate to heavily exuding partial and full-thickness wounds.

Both devices are biocompatible, exhibit absorbent properties, maintain a moist environment for optimal wound healing,

permit intact removal and have the same recommended frequency of dressing changes.

Both devices have a similar range of product sizes, are available in flat dressing and rope variants, are sterilised by gamma irradiation, and have similar contraindications.

Although there are some minor differences between the devices these differences are minor and raise no new questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 30 2003

Mr. John Green
Quality Assurance and
Regulatory Affairs Manager
Advanced Medical Solutions Ltd.
Road Three
Winsford Industrial Estate
Winsford, Cheshire
CW7 3PD, England

Re: K024298
Trade/Device Name: Antimicrobial Alginate Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: April 9, 2003
Received: April 14, 2003

Dear Mr. Green:

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. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. 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 may be obtained 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

K024298

510(K) NUMBER (IF KNOWN): K024298

DEVICE NAME: Antimicrobial Alginate Dressing

INDICATIONS FOR USE:

Advanced Medical Solutions Ltd's Antimicrobial Alginate Dressing is an effective barrier to bacterial penetration. The barrier functions of the dressing may help reduce infection in moderate to heavily exuding partial and full-thickness wounds including: pressure ulcers, venous ulcers, diabetic ulcers, donor sites, traumatic and surgical wounds.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use ____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Miriam C. Provost

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

510(k) Number K024298