

K991287

JUN 29 1999

**Attachment 2**

**Summary of Safety and Efficacy Summary of  
Advanced Medical Solutions Group plc  
Spyrogel® Hydrogel Wound and Burn Dressing SA**

**Manufacturer:** Advanced Medical Solutions plc  
Road Three, Winsford Industrial Estate  
Cheshire CW7 3PD, United Kingdom

**Regulatory Affairs Contact:** Christopher Oakes, Manager

**Telephone:** 44 1606 863 500

**Date Summary Prepared:** April 13, 1999

**Device Trade Name:** Spyrogel® Hydrogel Wound and Burn Dressing SA.

**Common or Usual Name:** Dressing, Wound and Burn, Hydrogel

**Classification:** Wound Dressings, currently unclassified by FDA.

**Description:** Advanced Medical Solutions Group plc Spyrogel® Hydrogel Wound and Burn Dressing SA are supplied individually packaged in medical grade foil pouches suitable for gamma irradiation. They are supplied to the market place as sterile dressings.

The intelligent film is as commercially distributed in the USA under 510(k) (K981753) June 30, 1998.

The dressings are sterilized by gamma irradiation. Isotron Laboratories provided Dose Mapping per ISO 11137, validation was undertaken in accordance with ISO 11137 Method 1. The verification dose required for a Sterility Assurance Level (SAL) of  $10^{-6}$  is 23.4 kGy. Sterilization validation data is on file at Isotron Laboratories.

Bioocompatibility testing has been performed in accordance with ISO10993-1 Biological Evaluation of Medical Devices - Part 1 Guidance on Selection of Tests First Edition. Data and Safety evaluation is as that submitted with already approved 510(k)'s K981753 and K982804. No components or raw materials have changed therefore no resubmission of toxicity data is required.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUN 29 1999

Mr. Christopher Oakes  
Regulatory Affairs Manager  
Advanced Medical Solutions plc  
Road Three, Winsford Industrial Estate  
Cheshire CW7 3PD  
United Kingdom

Re: K991287  
Trade Name: Spyrogel Hydrogel Wound and Burn Dressing  
Regulatory Class: Unclassified  
Product Code: MGP and MGQ  
Dated: April 13, 1999  
Received: April 14, 1999

Dear Mr. Oakes:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

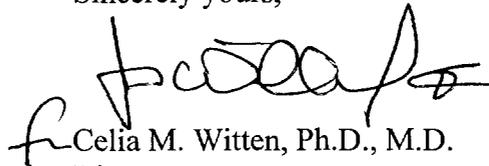
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 – Mr. Christopher Oakes

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Celia M. Witten', with a stylized flourish at the end.

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

Enclosure

510(k) Number (if known): K991287

Device name: Advanced Medical Solutions Group plc, Spyrogel Hydrogel Wound and Burn Dressing SA

**Indications For Use:**

Advanced Medical Solutions Group plc Spyrogel Hydrogel Wound and Burn Dressing SA is intended for OTC use on:

Superficial wounds such as, minor cuts, lacerations and minor burns and scalds

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

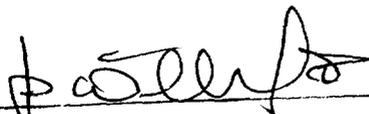
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

OR Over The Counter Use X

(Optional Format 1-2-96)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of General Restorative Dev  
510(k) Number K991287