

JUN 11 1999

K991630

Attachment 3**Summary of Safety and Efficacy Summary of
Advanced Medical Solutions Silicone Scar Management Sheet**

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

Regulatory Affairs Contact: Christopher Oakes, Manager

Telephone: 44 1606 803 500

Date Summary Prepared: May 25th, 1999

Device Trade Name: Silicone Gel Scar Management Sheet

Common or Usual Name: Silicone Gel Sheeting

Classification: Currently unclassified by FDA.

Description: Advanced Medical Solutions Silicone Scar Management Gel sheet is a soft, self-adhesive, semi-occlusive sheet made from medical grade silicone with a polyurethane film backing paper and a non siliconised polyester release paper.

The primary function of the dressing is to aid in the management of both existing and new hypertrophic and keloid scarring on scars resulting from burns, general surgical procedures and trauma wounds.

The Advanced Medical Solutions Silicone Scar Management Sheet comes in two sizes 3in. x 4in. and 1in. x 4in. the sheet may be cut or trimmed to the desired shape or size prior to placement on the scar, also two or more sheets may be placed together to cover a scar area that is greater than the area of a single sheet.

The Advanced Medical Solutions Silicone Scar Management Sheet is self adhesive but can also be secured by a lightly conforming bandage or tape if so desired.

The gel sheets are supplied either sterile or non-sterile in foil laminated sterilizable pouches.

Intended Use: The Advanced Medical Solutions Silicone Scar Management Sheet intended for the management of old and new hypertrophic and keloid scarring on scars resulting from burns, general surgical procedures and trauma wounds.

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Residual Limits (Federal Register June 1978)

ETO: 100ppm
ECH: 100ppm
EG: 2000ppm

INTENDED USE AND DIRECTIONS FOR USE

The Advanced Medical Solutions Silicone Scar Management Sheet intended for the management of old and new hypertrophic and keloid scarring on scars resulting from burns, general surgical procedures and trauma wounds.

Discontinue use if any infection of the wound is suspected and seek guidance from a health care professional.

Not for use on third degree burns.

Not to be used on open wounds.

Not for patients with dermatological conditions which disrupt the integrity of the skin in areas of coverage.

LABELS AND PRODUCT LABELING

Package labeling is presented in Attachment 1. Currently no promotional literature is available for the device.

- F. A STATEMENT INDICATING THE DEVICE IS SIMILAR TO AND/OR DIFFERENT FROM OTHER PRODUCTS OF COMPARABLE TYPE IN COMMERCIAL DISTRIBUTION, ACCOMPANIED BY DATA TO SUPPORT THE STATEMENT. THIS INFORMATION MAY INCLUDE AN IDENTIFICATION OF SIMILAR PRODUCTS, MATERIALS, DESIGN CONSIDERATIONS, ENERGY EXPECTED TO BE USED OR DELIVERED BY THE DEVICE, AND A DESCRIPTION OF THE OPERATIONAL PRINCIPLES OF THE DEVICE.

The Advanced Medical Solutions Silicone Scar Management Sheet is essentially similar to other devices approved by the FDA under the device classification, Elastomer, Silicone for scar management. Predictive devices include Spenco Silicone Gel Sheet 510(k) K981902, Spenco Medical Corp.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K991630
Trade Name: Silicone Gel Scar Management Sheet
Regulatory Class: Unclassified
Product Code: MDA
Dated: May 5, 1999
Received: May 11, 1999

Dear Mr. Oakes:

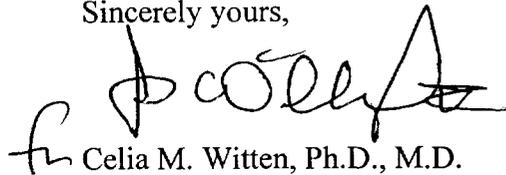
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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.

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". The signature is stylized and written in cursive.

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

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510(k) Number (if known): k991630

Device name: Advanced Medical Solutions Silicone Gel Scar Management Sheet

Indications For Use:

Advanced Medical Solutions Silicone Gel Scar Management Sheet is intended for OTC use for the management of:

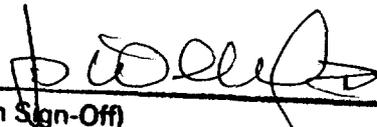
Old and new hypertrophic and keloid scarring on scars resulting from burns, general surgical procedures and trauma wounds.

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

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 Devices K991630
510(k) Number _____