

FEB 14 2002

Summary of Safety and Efficacy Summary of MedTrade Products Silicone Scar Gel

H. Safety & Effectiveness:

Manufacturer: MedTrade *Product's* Ltd, Electra House, Crewe Business Park
 Crewe, Cheshire. CW1 6GL. UK
 Contact: Jonathan Ranfield, Director, Quality Assurance & Regulatory Affairs
 Telephone: 011 44 1270 500019
 Prepared: November 28, 2001
 Device Trade Name: MedTrade Products Silicone Scar Gel
 Common or usual name: Silicone Scar Gel
 Classification Name: MDA Elastomer, Silicone, for Scar Management
 Description: MedTrade *Product's* Silicone Scar Gel is a self
 drying, topical gel made from medical grade silicone.

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.

MedTrade *Product's* Silicone Scar Gel comes in a 15g pump applicator, making it easy to apply to difficult areas. It is safe, hygienic and easy to use. It can be worn during the day or overnight.

The gel is supplied non-sterile.

Intended Use: MedTrade Products Scar Gel is 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.

Biocompatibility testing has been successfully completed per ISO/Tripartite guidelines.

MedTrade *Product's* Silicone Scar Gel is substantially equivalent in design, composition and function Kilo-cote Manufactured by Advanced Bio-Technologies 510(k) # K002488.

A table of comparative features may be found below. Labelling for substantial equivalent product may be found on pages 16 to 19.

COMPARATIVE FEATURES

Characteristics	MedTrade <i>Product's</i> Silicone Scar Gel	Advanced Bio-Technologies, Inc Kelo-cote Topical Gel
Composition	Self drying, topical gel made from medical grade silicone	Self drying, topical gel made from medical grade silicone
Appearance	Clear translucent gel	Clear translucent gel
Indications For Use	For Management of old and new hypertrophic and keloid scarring on scars resulting from burns, general surgical procedures and trauma wounds. Help Soften, Smooth and Flatten Scars	For Management of old and new hypertrophic and keloid scarring on scars resulting from burns, general surgical procedures and trauma wounds. Help Soften, Smooth and Flatten Scars
Sterilisation Method	Non Sterile	Non Sterile



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 14 2002

Mr. Jonathan Ranfield
Director, Quality Assurance and
Regulatory Affairs
Medtrade Products Limited
Electra House, Crewe Business Park
Crewe
Cheshire CW1 6GL
UK

Re: K014036

Trade/Device Name: MedTrade Product's Silicone Scar Gel
Regulatory Class: Unclassified
Product Code: MDA
Dated: November 28, 2001
Received: December 7, 2001

Dear Mr. Ranfield:

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.

Page 2 – Mr. Jonathan Ranfield

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), 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). 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,


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

Page 1 of 1

510(k) Number (if known) K 01 4036

Device Name: MedTrade *Product's* Silicone Scar Gel

Indications for Use:

MedTrade *Product's* Silicone Scar Gel is intended for the management of:

- Old and new hypertropic and keloid scarring on scars resulting from burns, general surgical procedures and trauma wounds
- Help Soften, Smooth and Flatten Scars

It is not indicated for use on:

- Open or infected wounds, scabs or stitches
- New wounds which have breached the dermis
- Materials present in the product do not contra-indicate topical (skin/scar) applications.
- The components do not contain animal ingredients.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use **X** Or Over The Counter Use **X**
(Per 21 CFR 801.190) (Optional Format 1-2-96)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K014036