

Enclosure F

510(k) Summary

Product Description

ScarEase is a non-invasive medical device that reduces hypertrophic and keloid scars resulting from surgical procedures and traumatic events. ScarEase may soften, smooth and/or flatten scars.

Substantial Equivalence

ScarEase Sheets are substantially equivalent Predicate Devices: Mepiform Adherent Silicone Dressing for Scar Care, 510(k) K974354; PMT Silicone Sheeting K935499; and Rejuveness K974380. Predicate Device for ScarEase Adhesive Gel is Kelocote K973572. ScarEase is made from identical liquid polysiloxane and/or elastomer materials and manufacturing processes as the predicate devices.

Intended Use

ScarEase Sheets and gel are indicated for use in the management of hypertrophic and keloid scars. In addition to the aforementioned statement, ScarEase may also prevent hypertrophic and keloid scarring.

Packaging and Labeling

ScarEase Sheets will be individually packaged rectangular-shaped sheets (.005" to .040" thickness, by 1.5" wide, by 4.0" long) heat-sealed in polyethylene tubing, enclosed in a fold-over (labeled) outer covering with descriptive product information, enclosed with a package insert and sealed with shrink-wrap.

ScarEase Gel will be available in 4 and 15 gram tamper-evident, labeled tubes. Each tube will be appropriately labeled to provide size, instructions for use and warnings. Each tube is generally placed into a descriptive display box stating product information and enclosed with a package insert.

Physical and Chemical Properties

The physical properties of ScarEase Sheets and Gel are the same as the predicate device in that equivalent materials will be used in manufacturing.

ScarEase sheets are made from Applied Silicone's calendared silicone sheeting material, durometer 50, shore A. For more information, see FDA master-file number MAF-607.

ScarEase Gel is an amorphous clear gel made with Nusil Technology's MED 4210 and 4211 infused with polydimethylsiloxane and silicone dioxide. For more information, see FDA master-file MAF 612.

Raw material are certified and tested to comply with the requirements of the manufacturer(s).



OCT 25 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Rob Fritzenkotter
Pillar Surgical
P.O. Box 8141
La Jolla, California 92038

Re: K991970
Trade Name: ScarEase Sheets and ScarEase Gel
Regulatory Class: Unclassified
Product Code: MDA
Dated: September 2, 1999
Received: September 7, 1999

Dear Mr. Fritzenkotter:

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.

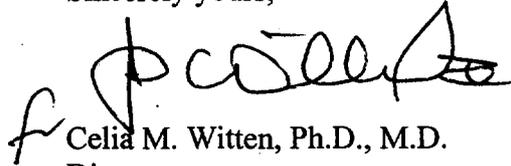
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

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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,



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): K991970

DEVICE NAME: ScarEase Sheets & ScarEase Gel

INDICATIONS FOR USE:

ScarEase Sheets and Gel are indicated for use in the management of hypertrophic and keloid scars.

ScarEase Sheets and Gel may prevent hypertrophic and keloid scarring.

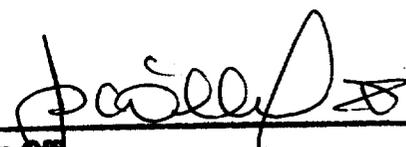
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use X
(Optional Format 1-2)



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K991970