

MAY 20 1998

K980563

13. 510(k) Summary

SKAR-KARE™-SHEET FOR THE TOPICAL MANAGEMENT OF HYPERTROPHIC OR KELOID SCARS

Contact: Target Health Inc.
310 Madison Avenue, 22nd Floor
New York, NY 10017

Tel: 212 681 2100
Fax: 212 682 0151

Sponsor: Life Medical Sciences, Inc.
379 Thornall Street
Edison, NJ 08837-2227 USA

Dr. Eli Pines

Tel: 732 494 0444
Fax: 732 494 6252

13.1. Device Name

SKAR-KARE™-SHEET is provided as follows:

- a. Trade Name - SKAR-KARE™-SHEET
- b. Common Name - Topical d for hypertrophic and keloid scars
- c. Classification Name – 21 CFR 880.5075 ELASTIC BANDAGE

13.2. Predicate Device/ Company Names and Addresses

The predicate device is listed below with its 510(k) clearance number.

REJUVENESS™ (formerly known as Silk*Skin)		RichMark International Corporation 100 Saratoga Village Blvd. Ballston Spa, NY 12020
---	--	--

13.3. Description of Device

SKAR-KARE™-SHEET is a soft, durable and washable elastic device for topical patient use over intact skin. It is not sterile. It is composed of a standard silicone sheeting (inert) in a flexible-link, ionic, micro-patterned appearance.

13.4. Intended Use

SKAR-KARE™-SHEET is intended for use in the topical management of hypertrophic and keloid scars. Do not use on open wounds.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 20 1998

Jules T. Mitchel, Ph.D.
Target Health, Inc.
Representing Life Medical Sciences, Inc.
310 Madison Avenue, 22nd Floor
New York, New York 10017

Re: K980563
Trade Name: SKAR-KARE™ Sheet
Regulatory Class: Unclassified
Product Code: MDA
Dated: April 13, 1998
Received: April 14, 1998

Dear Dr. Mitchel:

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.

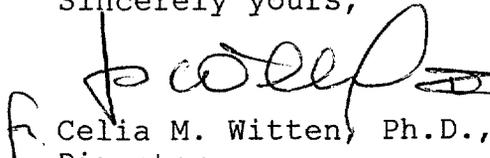
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

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

