JUL 20 '99

K991957

510k Summary for OTC version of CicaCare Gel Sheet

CicaCare Scar Management Gel Sheet is a topical silicone gel sheet similar in indications and application to Rejuveness and Clinicel. Respectively, Richmark International Corporation and Life Medical Sciences, Inc sell these products. The Indications for CicaCare include the following:

- For the management of hypertrophic and keloid scars
- May prevent the formation of hypertrophic and keloid scar formation
- For use only on intact skin
- For application to hypertrophic and keloid scars as a means of reducing the size and erythema of scars resulting from burns, trauma and surgery

Materials present in the product do not contraindicate topical (skin/scar) applications. The components do not contain animal ingredients. Additionally, the OTC use of this type of non-sterile silicone gel sheet is established via other currently marketed OTC non-sterile products.

CicaCare Gel Sheet is packaged in a medical grade heat seal package. The product is manufactured by Smith and Nephew Medical Limited of Hull England. Ingredients are procured from Dow Corning. This is the same formulation and manufacturing process as described in our document K935803. OTC distribution of the non-sterile version is the only change from K935803.

Signature

Date

7-6-99

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 20 1999

Mr. Jim Irvin
Vice President, Quality Assurance
and Regulatory Affairs
Smith & Nephew, Inc.
Wound Management Division
11775 Starkey Road
Largo, Florida 33773-4727

Re: K991957
Trade Name: Cicacare Management for Scars
Regulatory Class: Unclassified
Product Code: MDA
Dated: June 8, 1999
Received: June 10, 1999

Dear Mr Irvin:

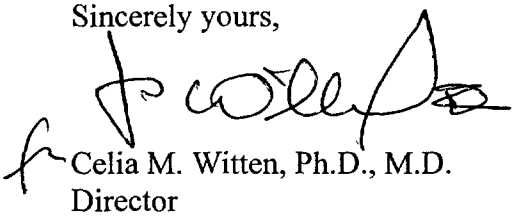
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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



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): K991957

Device Name: **CICACARE MANAGEMENT FOR SCARS**

Indications for Use:

- The device is intended for the management of hypertrophic and keloid scars.
- The device may prevent the formation of hypertrophic and keloid scars.
- The product is indicated for use only on intact skin.
- For covering Hypertrophic and Keloid Scars as a means of reducing the size and erythema of scars resulting from burns, trauma and surgery.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K991957

Prescription Use _____ OR Over-the Counter Use X

(Per 21CFR 801.109)

(Optional Format 1-2-96)