K974143

MAR 27 1998

510(k) SUMMARY
510(k) #: K974143

Trade Name: "KMC Ultra-Sil"

Common Name: Silicone Elastomer Sheet

Device Class: Unclassified

Classification Panel: General & Restorative Devices

Establishment Registration No.: To be filled

This summary of 510 (k) safety and effectivencss is submitted in accordance with 21CFR 807.92 and as defined in 21CFR 807.3

DEVICE DESCRIPTION and USE:

KMC Ultra-Sil Scar Management System is a thin, soft silicone sheet designed to be applied externally, in a non-invasive manner to healed keloid and hypertrophic scars. Scar area is to be washed and towel dried before application. KMC Ultra-Sil Scar Management System is applied to scar area with 1/2 inch overlap. Initial application to last 2-3 hours. Successive applications will increase contact by 1 hour each until 8 hour contact is reached. Application time of 20 hours is recommended.

MANUFACTURING:

KMC Ultra-Sil Scar Management System is manufactured using essentially the same silicone materials and industry manufacturing practices as re claimed SE product, Degania Silicone Sil-K.

SUBSTANTIAL EQUIVALENCE

KMC Ultr-Sil Scar Management System is substantially equivalent to Degania Silicone Sil-K, 510 (k) No. K971482.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 27 1998

John Harrison, Ph.D.
Technical/Regulatory Consultant
KMC International
5662 Calle Real, #331
Goleta, California 93117

Re: K974143
Trade Name: Ultra-Sil Scar Management System
Regulatory Class: Unclassified
Product Code: MDA
Dated: February 24, 1998
Received: March 2, 1998

Dear Dr. Harrison:

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

K974143

510(k) Number (if known): K974143

Device Name: "KMC Ultra-Sil Scar Management System"

Indications For Use:

KMC Ultra-Sil Scar Management System is a thin, spft silicone sheet designed for non-invasive application for keloid and hypertrophic scar management.

KMC Ultra-Sil Scar Management System is intended to be used only on healed scars.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use___ OR Over-The-Counter Use ✓
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K974143