OCT 21 1997 K973572

TAB G

510(k) Summary

Substantial Equivalence:

Kelocote Scar Gel and Kelocote Laser Gel are topical silicone elastomer products that are substantially equivalent to Kelocote Gel of Allied Biomedical. Allied Biomedical's kelocote was found SE to PMT's Gel Sheeting.

Intended Use:

The intended use of Kelocote Scar and Kelocote Laser Gels are for the management of hypertrophic scars and associated erythema which is commonly associated with scars in the first few months post trauma. Kelocote Scar Gel is applied in a very thin coat and the excess is wiped away. This forms a thin sheet on the skin which is very nearly invisible.

Physical and Chemical Properties:

Kelocote Gel is described as an amorphous paste with minimal to no elasticity or strength. Kelocote Gel in one form will contain Titanium Oxid or Zinc Oxide for color and concistency. Kelocote is manufactured from Applied Silicone's LSR-30 and or Nusil Technology's MED 4210 and 4211 Silicone Rubber MAF 612.

Package Description:

Packaging will consist of aluminum tubes of varying volumes from 1/6 ounce to 2 ounces. Tubes will be blind mouth with crimped ends. Tubes will be shipped individually or in boxes of 12 in corrugated protective outer boxes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

Ms. Kathy Hanson Richardson
Regulatory Affairs
Hanson Medical Inc.
19325 58th Place N.E.
Seattle, Washington 98155

OCT 21 1997

Re: K973572
Trade Name: Kelocote Scar Gel and Kelocote Laser Gel
Regulatory Class: Unclassified
Product Code: MDA
Dated: September 10,1997
Received: September 19, 1997

Dear Ms. Richardson:

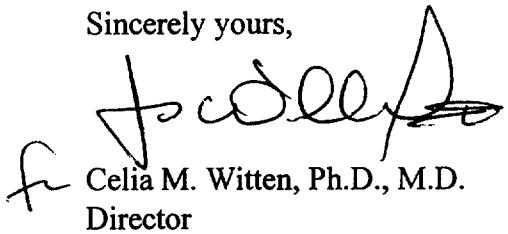
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 requirements , 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): K973572

Device Name: KELOCOTE SCAR GEL, KELOCOTE LASER GEL

Indications For Use:

KELOCOTE SCAR GEL:

FOR THE MANAGEMENT OF HYPERTROPHIC SCARS AND KELOID SCARS AND ASSOCIATED ERYTHEMA SECONDARY TO ANY TRAUMA CAUSING SCARS

KELOCOTE LASER GEL:

FOR THE MANAGEMENT OF HYPERTROPHIC SCARS AND KELOID SCARS AND ERYTHEMA SECONDARY TO LASER RESURFACING

(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 K973572

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

(Optional Format 1-2-96)