

APR 14 1998

510(k) SUMMARY

Submitter's Data:

Capital Marketing Technologies, inc.
3630 South Interstate 35, Suite A
Waco, Texas 76706
Telephone: 1-800-887-3370 or (254) 662-1752
Fax: (254) 662-1760.
Contact person(s): John Snyder or Vonna Muesse
Date prepared: November, 1998

State of intended use:

RETOUCH™ Silicone Gel Pads are designed to be worn on the skin for limited periods of time to reduce the appearance of healed hypertrophic and keloid scars. This is not a wound covering or dressing and should be worn 2-3 hours the first day and increase usage 1-2 hours each additional day, not to exceed 12 hours per day for 2-9 months depending on the type and severity of the scar.

Device Description:

RETOUCH™ Silicone Scar Reduction Sheets are soft, slightly adherent silicone gel sheets that are applied over healed hypertrophic and/or keloid scars. The sheets are not made of medical grade silicone and are not sterile. The sheets are rectangular and come in three sizes, 3.5 cm x 7 cm, 7 cm x 10.5 cm and 10.5 cm x 14 cm. They are approximately .125 of an inch thick. The customers will determine which size sheet is best for their own application. A sheet will not remove or eliminate the scar but will flatten and soften the scar tissue and help improve and regain the natural skin color.

The sheets are not for use on an open wound, are not sterile but can be washed. They are to be temporarily used on old or new healed hypertrophic or keloid scars and can be cut to other shapes if necessary.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 14 1999

Mr. John Snyder
Director of Research and Development
Capital Marketing Technologies, Inc.
3630 South Interstate 35, Suite A
Waco, Texas 76706

Re: K984213
Trade Name: Nearly Me® Retouch™ Silicone Scar Reduction Sheets
Regulatory Class: Unclassified
Product Code: MDA
Dated: February 26, 1999
Received: March 1, 1999

Dear Mr. Snyder:

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.

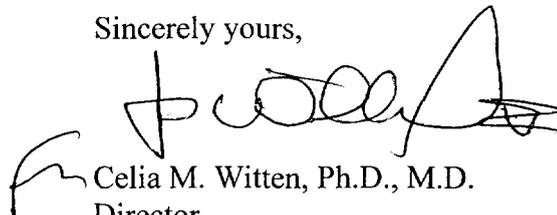
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

A handwritten signature in black ink, appearing to read 'Celia M. Witten', with a stylized flourish at the end.

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

K984213

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510(k) Number (if known): K984213

Device Name: NEARLY ME(R) RETOUCH(TM) Silicone Scar Reduction Sheets

Indications For Use:

NEARLY ME(R) RETOUCH(TM) Silicone Scar Reduction Sheets are soft durable silicone sheets designed to be worn on the skin for limited periods of time to reduce the appearance of hypertrophic and keloid scars.

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

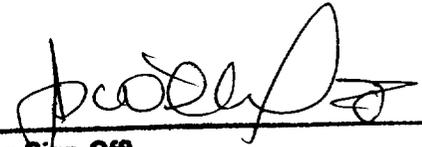
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use X

(Optional Format 1-2-96)



(Division Sign-Off)
Division of General Restorative Devices K984213
510(k) Number _____