

K 972597

OCT - 1 1997

510(k) Notification

New Beginnings™ GelShapes™ & Amend™

July 8, 1997

PMT® Corporation

Premarket Notification [510(k)]

Summary

Submitters name: PMT CORPORATION

Submitters Address: PMT Corporation
1500 Park Road
Chanhassen, MN 55317

Phone: (612) 470-0866

Fax: (612) 470-0865

Contact name: Steve Trinter

Date: July 8, 1997

Trade name: PMT® New Beginnings™ GelShapes™ & Amend™

Common name: Gel Sheeting

Classification name:

Equivalent device(s):

ReJuveness, McGhan Medical Corporation, Geligne Medical, Medical Z, CUI Corporation, Biodermis produce equivalent devices to those offered by PMT Corp.

Device Description:

PMT®'s Model 5100 New Beginnings™ GelShapes™ & Amend™ consist of a solid piece of low durometer medical grade silicone with a thin, high durometer silicone backing. Certain GelShapes™ & Amend™ also have reinforcement material for added strength. The silicone gel sheeting is used on hypertrophic or keloid scars in order to soften or lighten the color of these scars. The model 5100 New Beginnings™ GelShapes™ & Amend™ are used only externally and on intact skin.

This is a product which is commonly used by physicians treating hypertrophic or keloid scars, but is also now available at pharmacies and through direct phone orders.

While ^{MANAGEMENT}of keloid and hypertrophic scars by gel sheeting is a common procedure that has been around for many years, we have included a number of different articles within this submission for the reviewer.

The PMT New Beginnings™ GelShapes™ & Amend™ are packaged in a pouch constructed of Tyvek and Mylar. The package will employ a chevron opening feature.

The PMT New Beginnings™ GelShapes™ & Amend™ are provided sterile or nonsterile. The type of sterilization is 100% Ethylene Oxide. The sterilization method employed is the overkill method and validated to the terminal process endpoint probability of a nonsterile unit of 10^{-6} .



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

OCT - 1 1997

Mr. Steve Trinter
General Manager, Plastic Surgery Products Division
PMT® Corporation
1500 Park Road
Chanhassen, Minnesota 55317

Re: K972597
Trade Name: PMT® New Beginnings™ GelShapes™ & Amend™
Regulatory Class: Unclassified
Product Code: MDA
Dated: July 8, 1997
Received: July 11, 1997

Dear Mr. Trinter:

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.

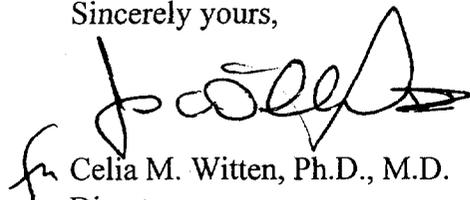
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

Page 2 - Mr. Steve Trinter

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". The signature is stylized and written over the printed name.

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): K972597

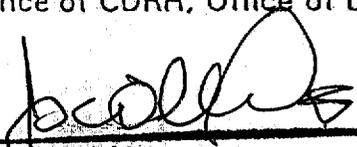
Device Name: PMT New Beginnings™ GelShapes™ and Amend™

Indications For Use:

Management 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)


(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K972597

Prescription Use _____
(Part 21 CFR 801.109)

OR

Over-The-Counter Use X

(Optional Format 1-2-96)