

Degania Silicone

TÜV

JUN 24 1997

Degania Silicone Ltd.

Degania Bet 15130, Israel. Tel: 972-6-755712, Fax: 972-6-709182



APPENDIX E

510(k) SUMMARY

K971482

Trade Name: Degania Silicone Sil-K
Common Name: Silicone Elastomer Sheet
Device Class: Unclassified
Classification Panel: General & Restorative Devices
Establishment Registration Number: 8030107

This summary of 510K safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

DEVICE DESCRIPTION AND USE:

Sil-K is a thin soft silicone sheet used to treat thick painful, itchy, red and raised hypertrophic or keloid scars.

Sil-K is designed to be used only after the skin has completely healed and is non invasive.

MANUFACTURING:

The Sil-K is manufactured from the same raw materials, from the same vendors and using the same manufacturing processes as our previous 510(k).

SUBSTANTIAL EQUIVALENCE:

We are Substantially Equivalent to ourselves.

16 April 1997
Date

Bette Lubin
Product Advisor &
Regulatory Affairs
Degania Silicone

24/29



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 24 1997

Ms. Bette Lubin
Product Advisor & Regulatory Affairs
Degania Silicone Ltd.
Degania Bet 15130
Israel

Re: K971482
Trade Name: Degania Silicone Sil-K
Regulatory Class: Unclassified
Product Code: MDA
Dated: April 16, 1997
Received: April 21, 1997

Dear Ms. Lubin:

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.

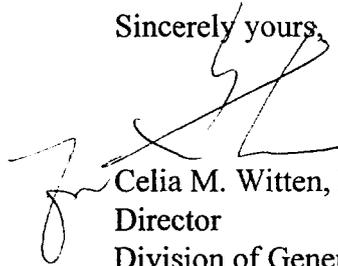
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

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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,



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



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TUV

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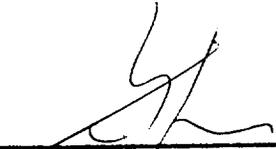
K971482

INDICATIONS FOR USE

Device Name: Degania Silicone Sil-K

Indications For Use: The Sil-K is designed and indicated for treating thick painful, itchy, red and raised hypertrophic or keloid scars.

Degania Silicone Ltd. is submitting a new Premarket Notification 510(k) as we wish to market the Sil-K OTC. The previous 510(k) number is K 914701.



 (Division Sign-Off)
 Division of General Restorative Devices
 510(k) Number K971482

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE

Concurrence of CDRH. Office of Device Evaluation (ODE)

Prescription Use: _____
(Per 21 CFR 801:109)

or

Over-The-Counter: ~~_____~~

(Optional Format 1-2-96)