Pfizer Consumer Healthcare
Pfizer Inc
201 Tabor Road
Morris Plains, NJ 07950
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K024160
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Pfizer

Consumer Healthcare

MAR 17 2003

12.0 510(k) SUMMARY

Date Prepared:	December 16, 2002
Applicant:	Warner-Lambert Company 201 Tabor Rd. Morris Plains, NJ 07950 Telephone: 973-385-5523 Fax: 973-385-4300
Contact Person:	John R. Jacobs Vice-President, Regulatory Affairs
Proprietary Name:	[Trade Name]
Common Name:	Silicone Elastomer Sheeting
Classification Name:	Elastomer, Silicone, for Scar Management
Product Code:	MDA
Predicate Devices:	Oleeva® Fabric (K982036), and (K023136) Bio Med Sciences, Inc. 1111 Hamilton St. Allentown, PA 18101
Description:	[Trade Name] is a self-adhesive, fabric-backed, semi-disposable silicone sheet. The main component of the product is a proprietary material called Silon®. The basic Silon material is made from a blend of medical grade silicone and polytetrafluoroethylene ("PTFE") in the form of an interpenetrating polymer network ("IPN"). The structure of the product allows very soft and fragile silicone gels to be formed into thin membranes with increased physical strength and durability. [Trade Name] is designed to improve the appearance of existing hypertrophic scars or keloids, when worn daily for three months. Additionally, if worn on newly-healed, dry scars, it may prevent or decrease the formation of hypertrophic scars and keloids.

	[Trade Name] is not sterile and does not contain antibiotics. [Trade Name] is not intended for use on open wounds. Each package of [Trade Name] contains 30 individual sheets (1.5" x 3"). Each sheet can be cut to fit the size of the scar or applied side-by-side, depending on the size of the scar.
Intended Use:	[Trade Name] silicone sheeting is indicated for the management of hypertrophic scars and keloids. Consistent use of [Trade Name] can reduce hypertrophic scarring and keloid formation, resulting from surgical or traumatic injury of the skin. [Trade Name] may be useful as a prophylaxis after surgical or traumatic dermal injury to aid in the prevention of hypertrophic scars and keloids.
Technological Characteristics:	[Trade Name] and the predicate devices are technologically and functionally identical. All devices have a skin-contacting surface of medical grade silicone with an internal matrix of PTFE, which increases the physical strength and durability of the product. In addition, [Trade Name] and the predicate devices have a non-skin contacting fabric backing, which makes the products convenient to wear under clothing.
Performance Data:	Not applicable
Biocompatibility Testing:	When tested according to the ISO 10993 guidelines, [Trade Name], was found to be non-sensitizing (Kligman Maximization); non-irritating (Intracutaneous Injection); and, non-cytotoxic (MEM Elution Cytotoxicity

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 17 2003

Warner-Lambert Company
Dina Russello
Director, Regulatory Affairs
201 Tabor Road
Morris Plains, New Jersey 07950

Re: K024160
Trade/Device Name: Silicone Sheeting
Regulation Name: Elastomer, silicone for scar management
Regulatory Class: Unclassified
Product Code: MDA
Dated: December 16, 2002
Received: December 17, 2002

Dear Ms. Russello:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

13.0 STATEMENT OF INDICATIONS FOR USE

510(k) Number: K024160

Device Name: [Trade Name] Silicone Sheeting

Indications for Use: [Trade Name] silicone sheeting is indicated for management of hypertrophic scars and keloids.

Consistent use of [Trade Name] can reduce hypertrophic scarring and keloid formation, resulting from surgical or traumatic injury of the skin.

[Trade Name] may be useful as a prophylaxis after surgical or traumatic dermal injury to aid in the prevention of hypertrophic scars and keloids.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K024160

Prescription Use_____ OR Over-The-Counter Use X
(Per 21 CFR §801.109)