

MAR 30 1998

**510(k) SUMMARY: Silgel™ Topical Gel Sheet**

**1. Name and address of Contact person**

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Douglas  
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Date of preparation: October 31, 1997

**2. Device Identification**

Trade Name: Silgel™ Topical Gel Sheet  
Common or Usual Name: silicone gel sheet  
Classification Name: Not classified

**3. Predicate Devices**

The predicate devices are all silicone topical gel sheets and include:  
Spenco Silicone Gelsheet, a pre-enactment device  
Silastic Soft Sheeting, (K894226) [January 3, 1990]  
Epi-Derm Silicone Gel Sheeting, [510(k) number unknown]  
New Beginnings Topical Gel Sheeting, [510(k) number unknown]  
DermaSof Gel Sheeting, [510(k) number unknown]  
Cica-Care Adhesive Gel Sheet, [510(k) number unknown]

**4. State of Intended Use**

Silgel™ is intended for use in the treatment and control of hypertrophic and keloid scars, prophylactic management of healed incisions and as a splint lining insert to relieve friction on newly healed scars.

**5. Device Description**

Silgel™, Topical Gel Sheet, consists of a durable medical grade silicone reinforced with polyester mesh. Sheets are protected on one side by a film which is removed before use and on the other by a paper backing. Sheets are individually packaged in grip seal bags. A sheet can be trimmed to the desired shape prior to placement on the scar. It is secured by wrapping with either gauze and hypoallergenic adhesive tape, light conforming crepe or tubular bandages, or compression garments. Firm pressure is not required for a therapeutic effect.

{ } = Proprietary Information Contained Within

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## 6. Technological Characteristics

Silgel™ and the predicate devices consist of a thin sheet of silicone gel. Silgel™ and several of the predicate devices contain a reinforcing mesh, while Cica-Care is supported by a silicone membrane. All products are comfortable, semi-occlusive, slightly adhesive and durable. Although the mechanism of action is not completely characterized, the effectiveness of silicone gel sheeting products has been repeatedly demonstrated in the clinical situation.

## 7. Testing Summary

### *Component Testing:*

The silicone gel raw material, cured under conditions similar to those used for the finished device, has been subjected to the biocompatibility tests as defined in ISO 10933 for skin contact devices. The biocompatibility data demonstrate that the silicone gel meets all test requirements.

### *Final Product Testing:*

Final product configuration was subjected to the following test battery.

Hemolysis Test: In Vitro Hemolysis Test by Direct Contact

Cytotoxicity Test: MEM Elution Method

Pyrogenicity Test: Limulus Amebocyte Lysate (LAL) Test

All test were acceptable demonstrating that the product is safe for its intended use.

The effectiveness of silicone gel sheet products in the management and prophylaxis of hypertrophic and keloid scars has been demonstrated by numerous clinical studies. The intended use and instructions for use for Silgel™ are consistent with the clinical findings of these studies.

## 8. Rationale for Substantial Equivalence Determination

A comparison of the technological characteristics of Silgel™ Topical Gel Sheet shows that it is a silicone gel sheet as are all predicate devices. The intended use in control and management of hypertrophic and keloid scars is common with these predicate devices. As with Cica-Care, Silgel™ is indicated for prophylactic therapy in healed incisions and wounds. It is also indicated as a splint lining to relieve friction on newly healed scars similar to Spenco Silicone Gelsheet. The instructions for use are essentially the same for all products. As with the predicate devices, Silgel™ can be cleaned routinely during the course of clinical management. All product labels discuss the potential skin complications associated with clinical use including rash and irritation. Unlike predicate devices, Silgel™ is not provided sterile nor is this considered to be a requirement for product safety and efficacy since it is only intended for use on intact skin. Based on this information, Silgel™ can be considered substantially equivalent to the predicate devices.



Food and Drug Administration  
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Rockville MD 20850

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MAR 30 1998

Re: K974172  
Trade Name: Silgel™ Topical Gel Sheet  
Regulatory Class: Unclassified  
Product Code: MDA  
Dated: March 9, 1998  
Received: March 11, 1998

Dear Mr. Evans:

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.

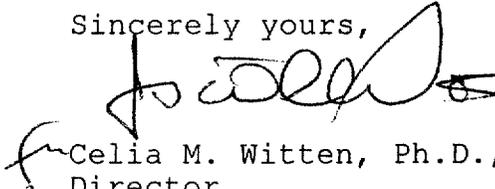
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

Page 2 - Mr. J.A. Evans

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): K974172

Device Name: Silgel<sup>TM</sup> Topical Gel Sheet

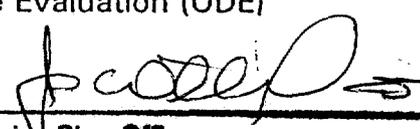
Indications For Use:

Silgel<sup>TM</sup> device is intended for use in the management of hypertrōphic and keloid scars. It can also be used for the prophylactic management of healed incisions for the prevention of hypertrophic or keloid scars.

Silgel<sup>TM</sup> helps relieve friction on newly healed scars when used as a splint lining insert.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of **General Restorative Devices**

510(k) Number K974172

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use X

(Optional Format 1-2-96)