

510(k) Submission: Silgel Topical Gel Sheet

**RMI**K 960254  
Rofil Medical USA, Inc.**Rofil Medical USA, Inc.**

APR - 2 1996

**510(k) SUMMARY: Silgel Topical Gel Sheet****1. Name and address of Contact Person**

William E. Stovall  
Rofil Medical USA, Inc.  
26856 Oak Hollow Road  
Laguna Hills, CA 92653

Telephone: (714) 348-8419  
FAX: (714) 348-8419

Date of Preparation: January 8, 1996

**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 management 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 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 desire 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.

K960254

510(k) Submission: Silgel Topical Gel Sheet

Rofil Medical USA, Inc.

## 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 conformable, 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 tests 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 the 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.