AUG - 5 1999

K984029

Nagor

510(k) SUMMARY: Silgel™ STC-S

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

J.A.Evans, Technical Director
Nagor Limited
P.O Box 21
Douglas
Isle of Man
British Isles
IM99 1AX

Tel: +44 (0) 1624 625556
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Date of preparation: 4 November 1998

2. **Device Identification**

Trade Name: Silgel™ STC-S
Common or Usual Name: Silicone gel
Classification Name: Not classified

3. **Predicate Devices**

The predicate devices are all silicone gels and include:
Kelocote Gel [510 (k) registration number: K954413]
Xeragel [510 (k) number unknown]
Zeraderm [510 (k) number unknown]
Scar Fade [510 (k) number unknown]
Spectragel [510 (k) number unknown]

4. **Statement of Intended Use**

Silgel™ STC-S is intended for use in the management of keloid and hypertrophic scars and associated erythema.

5. **Device Description**

Silgel™ STC-S consists of a high purity, medical grade silicone gel. The device will be sold non-sterile and supplied in aluminum tubes packaged into single unit cartons. Once applied to the skin according to the Instruction for Use the device does not need to be covered or held in place. Please note that the product is a device and not a pharmaceutical cream. It is not absorbed by the skin and functions as a membrane which retains moisture whilst permitting air to penetrate to the affected area.

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6. **Technological Characteristics**

Silgel™ STC-S consists of a single ingredient a high purity polydimethyl siloxane gel which is obtained by the hydrolysis of dimethyl, di-chlorosilane in the presence of an excess of water. The material is not cross-linked. Its special features include high purity, chemical inertness, high water repellence, low volatility, low surface tension, low order of toxicity and skin sensitisation which makes it ideal for providing an inert protective coating and repellent film on the skin.

7. **Testing Summary**

Component Testing:

The material has been evaluated for compliance with ISO 10993-1: 1997, Biological Evaluation of Medical Devices Part 1. Evaluation and Testing, for skin contact devices.

Final Product Testing:

The material has been evaluated for compliance with ISO 10993-1: 1997, Biological Evaluation of Medical Devices Part 1. Evaluation and Testing, for skin contact devices.

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

8. **Rationale for Substantial Equivalence Determination**

A comparison of the technological characteristics of Silgel™ STC-S shows that it is a silicone gel as are the predicate devices. Silgel™ STC-S is intended for the management of hypertrophic and keloid scars and associated erythema; in common with the predicate devices. The instructions for use are essentially the same for all products. As with the predicate devices, Silgel™ STC-S does not require to be held in place or covered. The Silgel™ STC-S product labels discuss the potential skin complications associated with clinical use. Silgel™ STC-S, in common with the predicate devices 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™ STC-S can be considered substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 5 1999

Mr. J.A. Evans
Technical Director
Nagor Limited
P.O. Box 21 Douglas
Isle of Man IM99 1AX
British Isles

Re: K984029
Trade Name: Silgel STC-S
Regulatory Class: unclassified
Product Code: MDA
Dated: May 4, 1999
Received: May 7, 1999

Dear Mr. Evans:

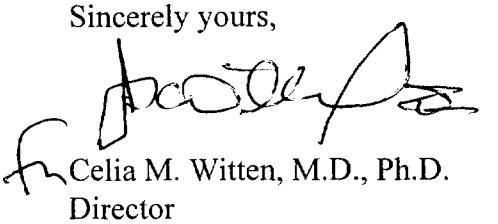
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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). You may, therefore, market the device, subject to the general control provisions of the Act. The general control 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.

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/dsma/dsmamain.html".

Sincerely yours,



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

Enclosure

510(k) Number (if known): K984029

Device Name: SILGEL™ STC-S

Indications For Use:

SILGEL™ STC-S is intended for use in the management of Keloid and Hypertrophic scars and associated erythema.

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(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 K984029

Prescription Use____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use X

(Optional Format 1-2-96)