

JUL 30 1999

K991968

## 510(k) Summary

Cica-Care Roll-On Gel is a topical liquid silicone gel made from medical grade silicone. The gel is applied via roller-ball technology. As a result, the gel can be applied to awkward areas of the body.

Cica-Care Roll-On Gel is available OTC and is non-sterile. The gel may also be recommended/specified by healthcare professionals for use in the management of scars.

Indications are:

- \* The device is intended for the management of hypertrophic and keloid scars.
- \* The device may prevent the formation of hypertrophic and keloid scars.
- \* The product is indicated for use only on intact skin.
- \* For application to Hypertrophic and Keloid Scars as a means of reducing the size and erythema of scars resulting from burns, trauma and surgery.

Materials present in the product do not contra-indicate topical (skin/scar) applications. The components do not contain animal ingredients.

Substantially equivalent products are contained in the following matrix.

Product	510(K)
Kelocote Allied Bio-Medical Corp	K954413
Silgel Biosil Ltd.	K960254
Rejuveness Rickmark International Corp.	K974380
Clinicel Life Medical Sciences, Inc.	



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUL 30 1999

Mr. Jim Irvin  
Vice President of Regulatory Affairs  
Smith & Nephew, Inc.  
Wound Management Division  
11775 Starkey Road  
Largo, Florida 33779-1970

Re: K991968  
Trade Name: Cicacare Roll-on Gel-Scar Management Liquid Gel  
Regulatory Class: Unclassified  
Product Code: MDA  
Dated: June 9, 1999  
Received: June 11, 1999

Dear Mr. Irvin:

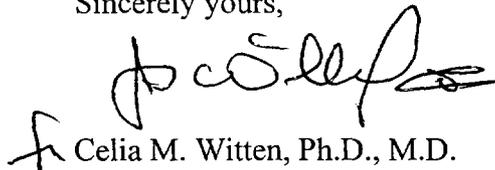
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 (Pre-market 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.

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,

A handwritten signature in black ink, appearing to read 'C. Witten', with a stylized flourish at the end.

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):

K991968

Device Name:

CICACARE ROLL-ON GEL

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- \* For application to Hypertrophic and Keloid Scars as a means of reducing the size and erythema of scars resulting from burns, trauma and surgery.

(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

K991968

Prescription Use \_\_\_\_\_

OR

Over-the Counter Use

X

(Per 21CFR 801.109)