DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Medical Z, S.A.
c/o Ms. Emalee G. Murphy
McKenna & Cuneo, L.L.P.
1900 K Street, N.W.
Washington, District of Columbia 20006-1108

JUL 29 1997

Re: K971916
Trade Name: Medigel Z™ Scar Management Gel
Regulatory Class: Unclassified
Product Code: MDA
Dated: May 23, 1997
Received: May 23, 1997

Dear Ms. Murphy:

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.

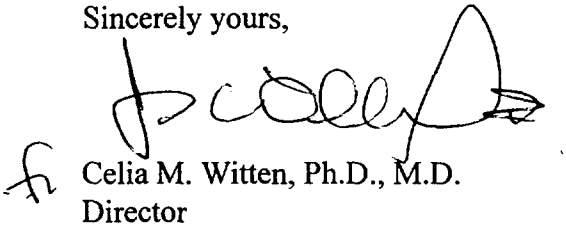
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

K971916

Appendix C

510(k) Summary
Medical Z, S.A.
Medigel Z™

I. General Information on Submitter: JUL 29 1997

Name:	Medical Z, S.A.
Address:	BP 39 - 55, rue de l'Église F-61110 Rémalard France
Telephone:	(33) 02 33 73 77 21
Fax:	(33) 02 33 73 78 88
Contact Person:	André Zagamé

Date Summary Prepared:	May 23, 1997

II. General Information on Device

Name:	Medigel Z™ Scar Management Gel
Classification Name:	Elastomer, Silicone, for Scar Management

III. Predicate Devices: Silipos® Tri Block Polymer Gel (K942695)

Smith & Nephew Rolyan Cica-Care™ Silicone Gel Sheet (K935803)

IV. Description of the Device:

The Medigel Z is a combination of a tri-block polymer and mineral oil. Medigel Z sheets are available in two thicknesses, 3 mm and 5 mm. The 3 mm sheets are 4 inches by 4 inches. The 5 mm sheets are available in three sizes: 8 by 8 inches, 12 by 16 inches, and 16 by 20 inches. The 5 mm sheets are lined with a fabric backing.

The Medigel Z is also available in four different sized elastic sleeves. The sleeves are 9.5 inches long and range from 12 to 55 inches in circumference. The Medigel Z is also available as an unlined finger-tube, a fabric lined sternal strap, and an elastic lined glove (open finger tips) and chin strap.

The Medigel Z also is available with an adhesive which eliminates the need for a compression bandage in most cases. The adhesive Medigel Z is available with or without a fabric backing and comes in sheets or circular pads. The "Mammopatch Gel Z" and "Abdopatch Gel Z" are fabric backed versions of the adhesive Medigel Z that are shaped specifically for use on the breast and abdomen.

V. Intended Use:

The Medigel Z products are indicated for temporary use in the management of hypertrophic scars and keloids resulting from wounds, trauma, or burns. The Medigel Z products are not wound dressings and are not intended to be used on open wounds. It is recommended that the products be used after the closing of a wound (8th to 10th day), or just after the first sign of hypertrophic scars.

VI. Technological Characteristics of Device Compared to Predicate Device:

The Medigel Z™ shares the same technological characteristics, and is manufactured with the same materials as the Silipos® Tri Block Polymer Gel, with the exception of the use of an adhesive to attach the device to the patient's skin. The Cica-Care™ gel, like the Medigel Z, uses an adhesive to attach the gel the body.

510(k) Number (if known): K971916

Device Name: Medigel Z Scar Management Gel

Indications For Use:

The Medigel Z products are indicated for temporary use in the management of hypertrophic scars and keloids resulting from wounds, trauma, or burns. The Medigel Z products are not wound dressings and are not intended to be used on open wounds. It is recommended that the products be used after the closing of a wound (8th to 10th day), or just after the first sign of hypertrophic scars.

(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 K971916

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)