

JUN

**SUBJECT: 510(k) SUMMARY K981353
PREMARKET NOTIFICATION [510(k)] SUBMISSION**

1. IDENTIFICATION

Date: May 27, 1999

Applicant: Avocet Polymer Technologies, Inc.
Address: 1112 Church Street
Huntsville, AL 35801

Applicant Telephone: 256/533-4201
Applicant Fax: 256/533-4805

Contact: Mary Capelli-Schellpfeffer
Tel. 256/533-4201 Fax 256/533-4805

2. NAME OF THE MEDICAL DEVICE

Proprietary name: Avogel®
Common/usual name: Hydrogel
Classification name: Dressing, Wound and Burn, Hydrogel
Regulation number: 878.4022
Medical specialty: General & Plastic Surgery
Product code: MGQ

3. SUBSTANTIALLY EQUIVALENT PRODUCTS

Silastic Soft Sheeting Dow Corning
P.O. Box 100
Arlington, TN 38002
K894226

Cica-Care Silicone Gel Sheet Smith & Nephew
11775 Starkley Rd.
Largo, FL 34649
K935803

NovaGel Sheeting Brennen Medical, Inc.
1290 Hammond Rd.
St. Paul, MN 55110
K963128

510(k) SUMMARY K981353, Page 2**4. DEVICE DESCRIPTION**

Avogel[®] is a sheet of hydrogel with a polyurethane film backing.

5. INTENDED USE

Avogel[®] is intended for use in the management of hypertrophic scars.

6. TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE

The device is indicated for surface dressing of intact and uninfected scarred skin identical to the predicate devices. The device offers user flexibility as it can be worn under a simple bandage, paper tape, ace wrap or flexnet as desired by the patient. The device may be worn without attachment by adhesives or wraps.

As with the predicate devices, the barrier function of healed skin is expected to be intact. Avogel[®] and the predicate devices provide similar physical, thermal and mechanical properties.

Clinical and molecular testing has shown equivalent clinical improvement using silicone and hydrogel dressings with reduction in firmness, pruritus, pain and tenderness. Molecular testing showed increased levels of IL-8, bFGF and GMCSF mRNA; while mean TGFβ and fibronectin mRNA decreased after treatment with both dressings. Both silicone and hydrogel dressing offered treatment for hypertrophic scars that was monitored at the clinical and molecular level with equivalent outcomes.

The limited indication statement of Avocet Polymer Technologies Gel does not raise new issues of safety in comparison to the predicate device. The barrier function of treated skin is expected to be intact during Avogel[®] use. This submission does not claim intended use for wound exudate absorption. Avogel[®] is not intended to be placed over open wounds. Avogel[®] is not intended to be placed in direct contact with body fluids (either from eyes, internally or from open wounds).



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 1999

Mary Capelli-Schellpfeffer, MD, MPA
Director
Avocet Polymer Technologies, Inc.
1112 Church Street
Huntsville, Alabama 35801

Re: K981353
Trade Name: Avogel®
Regulatory Class: Unclassified
Product Code: MDA and MGQ
Dated: March 25, 1999
Received: March 26, 1999

Dear Dr. Capelli-Schellpfeffer:

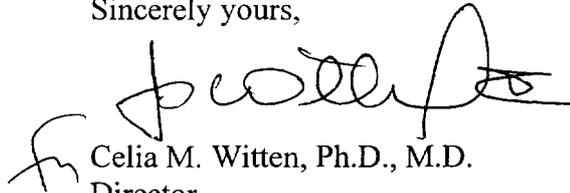
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 large, stylized initial 'C' and a horizontal line extending to the right.

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: **K981353**

Device Name: **Avogel®**

Indications for Use:

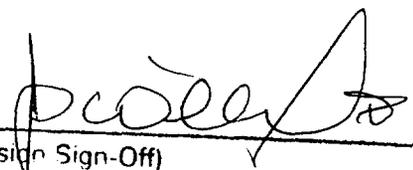
Avogel® is intended for use in the management of hypertrophic scars.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
Per 21 CFR 801.109

Over-The-Counter Use
(Optional Format 1-2-96)



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K981353