K971034

POREX SURGICAL INC.

4715 Roosevelt Highway, College Park, GA 30349-2417 USA
(404) 969-8145 • (800) 521-7321 • Fax: (404) 969-8045

JAN 20 1998

510(k) SUMMARY

Manufacturer and Submitter

Porex Surgical, Inc.
4715 Roosevelt Highway
College Park, GA 30349

Tel: (770) 969-8145
Fax: (770) 969-8045

Contact: Howard Mercer, Ph.D.

Date: May 30, 1997

Trade Name: MEDPOR® Ocular Conformer
Classification Name: Ophthalmic Conformer - Class II Device

Substantially equivalent to:
A) Ophthalmic Conformer marketed by Wilson Ophthalmic Corp.

Device description:

An ophthalmic conformer is used after surgery on the eye to prevent closure or adhesion. It is a cup shaped device that is slipped between the orbit and the eye lid to cause separation. Its inner surface is formed to approximate the outer curvature of the eye.

The ophthalmic conformer of this 510(k) is molded of Class VI. medical grade polymethyl methacrylate. It is sold in three sizes and it is sold non-sterile

Comparison with predicate device

The device of this submission is identical to the predicate device in all aspects except for minor dimensional changes

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 20 1998

Howard A. Mercer, Ph.D.
c/o Porex Technologies
500 Bohannon Road
Fairburn, GA 30213-2828

Re: K972034
Trade Name: Medpor Ocular Conformer
Regulatory Class: II
Product Code: 86 HQN
Dated: November 7, 1997
Received: November 10, 1997

Dear Dr. Mercer:

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) 594-4613. 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. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number : K972034

Device Name: Ophthalmic Conformer

Indications for Use:

The ophthalmic conformer is intended to be used as a post eye surgery device to prevent closure or adhesion during the healing process.

(PLEASE DO NOT WRITE BELOW THIS LINE)

Donna R. Lochner

(Division Sign-Off)
Division of Ophthalmic Devices

510(k) Number K972034

Prescription Use: X OR Over the Counter Use: ___
(Per 21CFR801.109)