JUL 16 2004

K040851

POREX
SURGICAL PRODUCTS GROUP

510(k) SUMMARY
(Revised 7-14-04)

Manufacturer and Submitter

Porex Surgical, Inc.
15 Dart Road
Newnan, GA 30265

Tel: (678) 479-1610
Fax: (678) 423-1437

Contact: Howard Mercer
e-mail: howard.mercer@porex.com

Date: February 27, 2004

Trade Name: Device Name: MEDPOR Attractor Magnetic Coupling System (MCS)

Class II Device
510(k) Number _____

Substantially equivalent to:

A. MEDPOR Ocular Peg System K971583
B. MEDPOR Ocular Screw K960859

Device description:

Titanium nitride coated stainless steel screw, ATTRACTOR SCREW, is designed to be placed into the MEDPOR implant, so that the head of the screw is placed at the anterior apex of the implant as it sits in the orbit. The flat head of the screw is flush with the surface of the implant and is covered with the overlying tissue.
Magnets of appropriate material, shape, and size to be imbedded into the posterior of the prosthetic eye. The magnets are designed small enough to remain entirely within the material (typically acrylic) of the prosthetic eye, and powerful enough to provide a coupling force between the implant and the prosthesis.

Indications for Use:

The MEDPOR ATTRACTOR Magnetic Coupling System is indicated for patients who have a MEDPOR Ocular Implant, and wish to gain improved prosthetic eye motility by coupling the ocular implant to the prosthetic eye.

NOTE: Improved prosthesis motility is a function of adequate implant motility, adequate coupling forces between the implant and the prosthesis, and adequate room in the socket for prosthesis motility. Not all patients will benefit from the use of the MEDPOR Attractor Magnetic Coupling System. Consider all factors affecting potential prosthesis motility when selecting patients for the MEDPOR ATTRACTOR Magnetic Coupling System.

Technological Characteristics:
Some physicians believe that it is necessary to mechanically couple the prosthesis to the implant in some manner to improve motility over an uncoupled prosthesis. The device that is the subject of this premarket notification uses magnetic force to accomplish the coupling between the orbital volume replacement implant and the eye prosthesis. During the manufacturing of the prosthesis, by an ocularist, one or more small

magnets are placed into the posterior of the prosthesis so that they are covered with a thin layer of acrylic. An attractor screw made of titanium nitride coated stainless steel is placed in the implant so that it is flush with the surface of the implant and becomes covered with tissue. When the prosthesis is placed on the implant, the magnet force between the magnets in the prosthesis and the screw in the implant provide a coupling force to enable the two to move in unison.

Prosthesis motility was measured on an anophthalmic patient who had undergone enucleation followed by placement of a MEDPOR® Sphere implant. The implant contained a titanium nitride coated steel screw insert placed anteriorly in the implant and the implant and insert were covered with Tenon's and conjunctiva. Prosthesis motility was measured with a prosthesis containing no magnet, and with the same prosthesis after placement of three different magnets of various strengths in the posterior surface of the prosthesis. Statistically significant improvement in lateral excursion motility ($P<0.0001$ with the strongest and $P=0.02$ with the second strongest magnet) were measured for the prosthesis.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 16 2004

Porex Surgical Products Group
c/o Mr. Greg Swords
Vice President, Technology and Development
15 Dart Road
Newnan, GA 30265-1017

Re: k040851
Trade/Device Name: MEDPOR® Attractor™ Magnetic Coupling System
Regulation Number: 21 CFR 886.3320
Regulation Name: Eye Sphere Implant
Regulatory Class: Class II
Product Code: HPZ
Dated: May 25, 2004
Received: May 27, 2004

Dear Mr. Swords:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer 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,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE

Applicant: Porex Surgical, Inc.
15 Dart Road
Newnan, GA 30265

Tel: (678) 479-1610
Fax: (678) 423-1437

510(k) Number: _____

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(PLEASE DO NOT WRITE BELOW THIS LINE)

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

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K040851