

K971583



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JUN 30 1997

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: April 29, 1997

Trade Name: MEDPOR® Ocular Screw and Accessories
Classification Name: Device is not classified

Substantially equivalent to:

A) The Ocular Screw and Accessories currently approved for sale by Porex Surgical.

Device description:

Titanium Screw

The screw is intended for single patient use. The Titanium Screw is composed of #6A1-4V ELI titanium which meets ASTM Standard F136-92. Three head sizes of 4.6 mm, 3.5 mm, and 2.5 mm will be available. The screw head contains a square hole to mate with the driver. The screw shaft and thread pattern is the same for all three head sizes.

The ocular screw is supplied non-sterile.

Screwdriver

The Screwdriver is manufactured of 316 stainless steel. The screwdriver tip is designed to mate with the square hole in the head of the titanium screw. The screwdriver is supplied non-sterile and is intended to be re-usable.

Drill Bit

The Drill Bit is a 1 mm diameter, 316 stainless steel, twist drill bit to be used for drilling a pilot hole for the screw. The Drill Bit is supplied non-sterile, and is intended to be re-usable.

Background for Product Use

After routine enucleation or evisceration of the eye by an ophthalmologist or oculoplastic surgeon, the void is filled with a MEDPOR® Surgical Implant in the form of a sphere or in the form of a conical shape. The muscles of the eye are routinely attached to the implant or a tissue covering to provide motility to the implant after healing has taken place. The surgeon then closes the conjunctiva around the anterior portion of the implant.

After the conjunctiva covering the implant heals and the swelling subsides, the surgeon refers the patient to an ocularist for fitting of a custom external eye prosthesis. The ocularist creates an artfully designed prosthetic eye. The prosthetic eye is made, for example, of a plastic such as polymethylmethacrylate (PMMA) and decorated to match the contra lateral real eye. The prosthesis is then worn by patient between the healed eye globe and eye lids in manner similar to a contact lens.

Many ophthalmologists and oculoplastic surgeons feel that simply inserting the prosthetic eye over the tissues covering the implant provides adequate motility and cosmesis. Others, however, believe enhanced motility can be achieved by a direct coupling of the orbital implant to the external prosthesis. The domed head of the screw is designed to fit in a socket made in the back of a custom ocular prosthesis to provide this direct coupling.

Comparison with predicate device

The device of this submission is identical to the predicate device except that there is a revision in the timing of the device use. In the predicate device indications it was instructed that the procedure should be performed after the ocular implant had become vascularized. The procedure has been modified to permit the device to be used at the time the enucleation operation is being performed.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 30 1997

Howard Mercer, Ph.D.
Porex Technologies Corp.
500 Bohannon Road
Fairburn, GA 30213

Re: K971583
Trade Name: MEDPOR® Ocular Screw and Accessories
Regulatory Class: II
Product Code: 86 MQU
Dated: April 29, 1997
Received: April 30, 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 (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 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 : K971583

Device Name: MEDPOR® OCULAR SCREW AND ACCESSORIES

Indications for Use:

The MCP® is indicated for patients with MEDPOR® Ocular Implants, who desire improved prosthetic eye motility via direct coupling of the implant to the prosthetic eye. Primary placement of the MCP® may occur during the initial reconstruction procedure, following attachment of the extraocular muscles to the ocular implant but before closing the Tenon's capsule and the conjunctiva layer. Secondary placement of the MCP may occur typically 3-6 months post enucleation after the ocular implant has become vascularized. Please read additional instructions below.

(PLEASE DO NOT WRITE BELOW THIS LINE)

Ausanna Jones / DEL

(Division Sign-Off)
Division of Ophthalmic Devices

510(k) Number K971583

Prescription Use: X
(Per 21CFR801.109)

OR

Over the Counter Use: _____