FEB 2 1 2003

ADMINISTRATIVE INFORMATION

Manufacturer Name:
MacroPore Biosurgery, Inc.
6740 Top Gun Street
San Diego, CA 92121

Official Contact:
Kenneth K. Kleinhenz
Director of Regulatory Affairs
Telephone (858) 458-0900
Fax (858) 458-0994

DEVICE NAME

Classification Name: Implant, Eye Sphear

Trade/Proprietary Name: MacroPore Surgical Barrier Film

ESTABLISHMENT REGISTRATION NUMBER

2031733

DEVICE CLASSIFICATION AND PRODUCT CODE

As shown in 21CFR 886.3320, an eye sphere implant is a device intended to be implanted in the eyeball to occupy space following the removal of the contents of the eyeball. These devices are classified as Class II. Eye sphere implants have been assigned Product Code HPZ.

INTENDED USE

The MacroPore Barrier Film is indicated for use as an orbital implant wrap to cover orbital implants used in enucleation surgery and to protect the surrounding orbital tissue from the surface of the implant.

DEVICE DESCRIPTION

Design Characteristics

MacroPore Surgical Barrier Film is a resorbable implant in sheet form manufactured from polylactides (PLA). MacroPore Surgical Barrier Film can be cut with scissors to the desired shape and size. MacroPore Surgical Barrier Film is fully malleable when heated to approximately 55°C (for example, by the use of sterile hot water), and thus can be conformed three dimensionally to most any anatomical orientation.

The MacroPore Surgical Barrier Film is provided in various shapes such as squares, rectangles, ovals, and circles. The MacroPore Surgical Barrier Film will be provided in sheets of 30mm x 30mm to 200mm x 200mm so that the surgeon may cut specific shapes and sizes. The thickness of the MacroPore Surgical Barrier Film will range from 0.05 mm to 1.0 mm. The MacroPore Surgical Barrier Film will be provided in solid sheets and in porous sheets that have pores that range in pore size from 0.5mm to 3.0mm with pores distributed randomly or uniformly throughout the film in an offset or aligned pattern. The pores are spaced at a distance of 1.5mm or greater

Material Composition

The MacroPore Surgical Barrier Film is fabricated from polylactide (PLA).

In Vitro Testing

Because the MacroPore Surgical Barrier Film is intended to be heated in the surgical suite to temperatures above the material's glass transition temperature to facilitate shaping to anatomic structures, testing was performed to determine the effect of prolonged heating in saline at 60°C on inherent viscosity. The testing demonstrates that viscosity stayed within an appropriate range over 120 minutes. Therefore, the relatively brief exposure anticipated during the surgical preparation of MacroPore Surgical Barrier Film is not expected to have a significant effect on its mechanical properties.

Aging testing was performed on MacroPore Surgical Barrier Film. Testing demonstrated that the MacroPore Surgical Barrier Film is strong enough for the indications for use.

Mechanical testing was performed on the MacroPore Surgical Barrier Film which determined the MacroPore Surgical Barrier Film to be substantially equivalent to the mechanical strengths of the predicate devices under indication for use conditions.

EQUIVALENCE TO MARKETED PRODUCT

MacroPore Surgical Barrier Film shares indications and design principles with the following predicate devices, which have been determined by FDA to be substantially equivalent to the following pre-amendment devices: Bio-Vascular Ocu-Guard and Bio-Eye II Orbital Implant; Class II medical devices that were cleared for marketing in the United States.

Indications For Use
MacroPore Surgical Barrier Film shares identical indications for use principles with the predicate devices as both the MacroPore Surgical Barrier Film and the predicate devices are indicated for the same surgical procedures.

Design and Materials
The physical designs of MacroPore Surgical Barrier Film and the predicate devices (Bio-Vascular Ocu-Guard and Bio-Eye II Orbital Implant) are substantially equivalent, consisting of thin semi-rigid sheets. The MacroPore Surgical Barrier Film and the bovine pericardium predicates also share design features of allowing for contouring. The MacroPore Surgical Barrier Film is fully contourable when heated to approximately 55°C. The dimensions of the predicate devices are also comparable to the MacroPore Surgical Barrier Film as both devices are provided in rectangular sheets that are several centimeters in size. The mechanical characteristics of the MacroPore Surgical Barrier Film are substantially equivalent to the predicate devices with respect to mechanical strength as measured by tensile and suture pull out testing. In addition to physical characteristics, both the predicate device and the MacroPore Surgical Barrier Film can be cut to specific shapes and sizes by the end user.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 21 2003

MacroPore Biosurgery, Inc.
c/o Kenneth K. Kleinhenz
6740 Top Gun St.
San Diego, CA 92121

Re: K023643
Trade/Device Name: MacroPore Surgical Barrier Film
Regulation Name: Eye Sphere Implant
Regulation Number: 21 CFR 886.3320
Regulatory Class: Class II
Product Code: MTZ
Dated: January 22, 2003
Received: January 23, 2003

Dear Mr. Kleinhenz:

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

Device Name: **MacroPore Surgical Barrier Film**

Indications for Use:
The MacroPore Barrier Film is indicated for use as an orbital implant wrap to cover orbital implants used in enucleation surgery and to protect the surrounding orbital tissue from the surface of the implant.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Division Sign-Off)
Division of Oph
Nose and Thro

510(k) Number K023643