JUL 1 2002

K021164

ADMINISTRATIVE INFORMATION

Manufacturer Name:	MacroPore, 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:	Plate, Fixation, Bone
Trade/Proprietary Name:	MacroPore OS Trauma

ESTABLISHMENT REGISTRATION NUMBER

2031733

DEVICE CLASSIFICATION AND PRODUCT CODE

As shown in 21CFR 888.3030 bone fixation appliances intended for use in orthopedic procedures are classified as Class II. They have been assigned Product Code HRS.

INTENDED USE

The MacroPore OS Trauma System is intended to maintain the relative position of weak bony tissue such as bone grafts, bone graft substitutes, or bone fragments from comminuted fractures. The MacroPore OS Trauma System is also indicated for cement restriction in total joint arthroplasty procedures.
Only when used in conjunction with traditional rigid fixation, the MacroPore OS Trauma System is intended to maintain the relative position weak bony tissue in trauma and reconstructive orthopedic procedures involving:

- Long bones
- Flat bones
- Short bones
- Irregular bones
- Appendicular skeleton
- Thorax

When used alone (without traditional rigid fixation), the MacroPore OS Trauma System is intended to maintain the relative position of bone grafts or bone graft substitutes in reconstructive orthopedic procedures involving:

- Tumor resections where bone strength has not been compromised
- Iliac crest harvests
- Ribs

This device is not intended for use in the spine. The device is not intended for load bearing indications unless used in conjunction with traditional rigid fixation.

Design Characteristics
MacroPore OS Trauma System is a resorbable graft containment system composed of various sized porous sheet and sleeves, non-porous sheets and sleeves, and associated fixation screws manufactured from poly (L-lactide-co-D,L-lactide) 70:30 (PLA). The MacroPore OS Trauma System is composed of MacroPore OS Trauma Protective Sheets, MacroPore OS Trauma Protective Sleeves, and MacroPore OS Trauma Screws.

The MacroPore OS Trauma Protective Sheets and Protective Sleeves can be cut with scissors to the desired shape and size. The MacroPore Power Pen can also be used to cut or shape the MacroPore OS Trauma to the desired shape or size. MacroPore OS Trauma Protective Sheets and Protective Sleeves are 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 Power Pen can also be used to cut or shape the MacroPore OS Trauma Protective Sheets and Protective Sleeves to the desired shape or size.

The MacroPore OS Trauma Protective Sheets can be rolled into a tube or used as a flat sheet. The MacroPore OS Trauma Protective Sheets and Protective Sleeves can be used either alone or in conjunction with internal bone fixation devices such as plates and screws, which also can serve to fixate the MacroPore OS Trauma and prevent dislocation.

The MacroPore OS Trauma Screws range in size from 2.0mm to 4.8mm in diameter. The MacroPore OS Trauma Protective Sheet is provided in sheets of 20 x 20 mm to 120 x 120 mm and will be provided in other sizes as needed for particular surgical procedures. The MacroPore OS Trauma Protective Sleeves are provided in lengths of 150mm to 5mm with diameters that range from 10mm up to 25mm. The MacroPore OS Trauma Protective Sheets and Protective Sleeves are provided with and without macroporous holes. The pore size ranges from 500 microns to 3000 microns in diameter, with pores distributed randomly or uniformly throughout the sheet/sleeve in an offset or aligned pattern. The thickness of the MacroPore OS Trauma Protective Sheets and Protective Sleeves ranges from 0.75 mm to 3.0 mm according to the orthopedic region to be treated.

Material Composition
The MacroPore*OS* Protective Sheet is fabricated from polylactic acid (PLA).

In Vitro Testing
Because the MacroPore OS Trauma Protective Sheet 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 OS Protective Sheet is not expected to have a significant effect on its mechanical properties.

Aging studies were performed on MacroPore OS Trauma System components. Testing demonstrated that the MacroPore OS Trauma Protective Sheet is as rigid and as strong as the predicate after 6 month of exposure. Mechanical testing was performed on the MacroPore OS Trauma Protective Sheets and MacroPore OS Trauma Screws. Testing determined the MacroPore OS Trauma System to be substantially equivalent to the mechanical strengths of the predicate devices under indication for use conditions.

Crystallinity was tested for by DSC (differential scanning calorimetery). This test measures the amount of heat energy that is absorbed by a material. A crystalline material will require more energy once it reaches it's melting point. This release of heat energy can be seen on a graph as a sharp spike and is referred to as a "melting endotherm". The tests ran on the sterile and non-sterile samples revealed no endothermic spikes, indicating that the implants are amorphous and non-crystalline.

EQUIVALENCE TO MARKETED PRODUCT

The MacroPore OS Trauma System shares materials, indications, and design principles with the following predicate devices which have been determined by FDA to be substantially equivalent to pre-amendment devices: MacroPore OS Protective Sheet, Synthes Resorbable Meshes and Sheets, and the MacroPore OS Protective Sheet.

Indications For Use

The MacroPore OS Trauma System shares substantially equivalent indications for use with the predicate devices.

Design and Materials

The design and materials of MacroPore OS Trauma System and the predicate devices (MacroProe OS, Synthes Resorbable Sheet and Mesh, and MacroPore OS Spine) are nearly identical as they all are made from resorbable polylactide (PLA) material and are provided in sheets and fixation screws of similar shapes and sizes. Both the predicate device and the MacroPore OS Trauma System Sheet have a semi-rigid construction with pores of similar diameter and spacing. The pore size and spacing of the predicate device is within the pore size and spacing specifications of the MacroPore OS Trauma System Protective Sheets. The dimensions of the predicate device are also comparable to the MacroPore OS Trauma System sheet as both devices are provided in rectangular sheets that are several centimeters in size. The mechanical characteristics of the MacroPore OS Trauma System are substantially equivalent to the predicate device with respect to tensile strength, shear strength, and rigidity as measured by the materials spring constant. In addition to physical characteristics, both the predicate device and the MacroPore OS Trauma Sheets can be shaped with warm water and 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

Mr. Kenneth K. Kleinhenz
Director of Regulatory Affairs
MacroPore Biosurgery
6740 Top Gun Street
San Diego, California 92121

JUL 1 2002

Re: K021164
Trade/Device Name: MacroPore OS Trauma
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation appliances and Accessories
Regulatory Class: Class II
Product Code: HRS
Dated: April 10, 2002
Received: April 11, 2002

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

for 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

Device Name: **MacroPore OS Trauma**

K021164

Indications for Use:

The MacroPore OS Trauma and the predicate device share substantially equivalent indications for use as they both are indicated for the reinforcing weak bony tissues in orthopeadic procedures and when used in conjuction with traditional rigid fixation. The MacroPore OS Trauma shares identical indications for use wording with the predicate device, MacroPore OS, with the exception of indications for rib bones. Specifically, the MacroPore OS Trauma is indicated for:

The MacroPore OS Trauma System is intended to maintain the relative position of weak bony tissue such as bone grafts, bone graft substitutes, or bone fragments from comminuted fractures. The MacroPore OS Trauma System is also indicated for cement restriction in total joint arthroplasty procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

Prescription Use Yes OR Over-The-Counter Use No

510(k) Number K021164