K083621

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SURGICAL PRODUCTS GROUP

FEB - 3 2009

510(k) SUMMARY

Date of Summary: January 30, 2009

Manufacturer and Submitter:

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

Tel: (678) 479-1610
Fax: (678) 479-4495

Contact: Mrs. Jerri Mann
E-mail: jerri.mann@porex.com

Trade Name: MEDPOR® Customized Surgical Implant

Class: II *21 CFR 874.3620 Ear, nose, and throat synthetic polymer material*

Product Code: JOF

Subsequent Product Code: GWO

Substantially equivalent to: MEDPOR Surgical Implant Material; Preformed Cranial & Facial Implants, K922489

Device Description:

MEDPOR Customized Surgical Implants are prescription devices tailored to a patient's individual requirements. MEDPOR Customized Surgical Implants are made from the same biocompatible pure porous high-density polyethylene (pHDPE) material as all MEDPOR Surgical Implants. An advantage of (pHDPE) is that the surrounding body tissue grows into the porous matrix, so the implant becomes integrated with and stabilized in the host tissues.

Indications for Use:

The MEDPOR Customized Surgical Implant is intended for the augmentation or restoration of bony contour in craniofacial defects.

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Technological Characteristics:

MEDPOR Customized Surgical Implant shapes can be created from CT scan data, a physical model, drawing or other information provided by a physician. MEDPOR Customized Surgical Implant shapes have the same intended use, are manufactured from the same material, can be trimmed with a blade in the sterile field, will accept plates and screws and are packaged the same as other MEDPOR Preformed Cranial and Facial Implants. MEDPOR Customized Surgical Implants are sterilized with Ethylene Oxide.

Substantial Equivalence:

MEDPOR Customized Surgical Implants are substantially equivalent to the predicate device MEDPOR Surgical Implant Material; Preformed Cranial & Facial Implants. The comparison table below details the similarities between MEDPOR Customized Surgical Implants and the predicate device:

Characteristic	MEDPOR Surgical Implant	MEDPOR Customized Surgical Implant	SE Y/N
Intended Use	For augmentation or restoration of bony contour in craniofacial defects.	For augmentation or restoration of bony contour in craniofacial defects.	Y
Materials	A linear, high-density polyethylene biomaterial	A linear, high-density polyethylene biomaterial	Y
Manufacturing Process	Preformed Shapes	Patient Specific Preformed Shapes	Y
Size Ranges/Specifications	Refer to Product Catalog	Customized according to a signed prescription form	Y
Shapes	Refer to Product Catalog	Customized according to a signed prescription form	Y
Packaging	Double peel pouched and put in a Clamshell or shelf box	Double peel pouched and put in a Clamshell or shelf box	Y
Sterile/Non-Sterile	Sterile	Sterile	Y
Sterilization Method	EO Gas	EO Gas	Y
Non-Pyrogenic Claim	YES	NO	N

Shelf-Life	10 years	10 years	Y
Biocompatibility	Yes	Yes	Y
Prescription Device	Yes - Sale by or on the order of a physician	Yes - Sale by or on the order of a physician	Y
Labeling	MEDPOR Surgical Implants including TITAN™ and BARRIER™ Implant Instructions For Use	MEDPOR CUSTOMIZED Surgical Implants	Y - Different only in that the labeling removes NON-PYROGENIC claim and has the statement "not tested for endotoxin".

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Porex Surgical, Inc.
c/o Jerri L. Mann
Regulatory Compliance Manager
15 Dart Road
Newman, GA 30265-1017

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Re: K083621
Trade/Device Name: MEDPOR® Customized Surgical Implant
Regulation Number: 21 CFR 874.3620
Regulation Name: Ear, nose, and throat synthetic polymer material
Regulatory Class: Class II
Product Code: JOF, GWO
Dated: December 3, 2008
Received: December 16, 2008

Dear Ms. Mann:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

M. B. Eydelman, MD

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K083621

Indications for Use

510(k) Number (if known): _____

Device Name: MEDPOR® Customized Surgical Implant

Indications for Use: The MEDPOR Customized Surgical Implant is intended for the augmentation or restoration of bony contour in craniofacial defects.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K083621