POREX
SURGICAL PRODUCTS GROUP

K091120

MAR 19 2010

510(k) SUMMARY

Date of Summary: March 11, 2010

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® CONTAIN™ Implant

Class: II, 21 CFR 872.3930 Bone grafting material

Product Code: NPK

Substantially equivalent to:

1) MEDPOR® Surgical Implant Material; Preformed Cranial & Facial Implants, K922489
2) GORE RESOLUT® ADAPT Regenerative Membrane, K051267
3) Osteo-Mesh TM-300 (Titanium Ridge Augmentation Mesh), K984230
4) Cytoplast™ Regentex Titanium 250, K972278
5) IMTEC/Titanium Mesh, K970841

Device Description:

MEDPOR CONTAIN Implant is a thin, highly porous, biocompatible semi-rigid sheet, made from the same biocompatible pure porous high-density polyethylene (pHDPE) material which allows for host tissue integration as other MEDPOR Surgical Implants. The MEDPOR CONTAIN Implant is designed to stabilize and support bone graft materials and provide space maintenance necessary for regenerative healing.

Indications for Use:

The MEDPOR CONTAIN Implant is intended to stabilize, support and provide space maintenance for bone graft materials in the maxilla, mandible, and zygoma.

Technological Characteristics:

The MEDPOR CONTAIN Implant can be used to contain, support and maintain the space for bone graft material that is used in the maxilla, mandible or zygoma to re-establish missing bone or establish new bone for support of dental implants. The MEDPOR CONTAIN Implant can be trimmed or cut to size and bent to conform to the needs of the individual patient. It may be stabilized with tacks, sutures, wires, or craniofacial screws. The MEDPOR CONTAIN Implant is manufactured from the same material, packaged, labeled and sterilized the same as all other MEDPOR Surgical Implant Material: Preformed Cranial and Facial Implants.

Substantial Equivalence:

The MEDPOR CONTAIN Implant shares indications and design principles with the following predicate devices:

Device Name	**Proposed Device** MEDPOR CONTAIN Implant	**Predicate Device #1** MEDPOR Surgical Implant Material; Preformed Cranial & Facial Implants	**Predicate Device #2** GORE RESOLUT ADAPT Regenerative Membrane	**Predicate Device #3** Osteo-Mesh TM-300 (Titanium Ridge Augmentation Mesh)	**Predicate Device #4** IMTEC/Titanium Mesh	**Predicate Device #5** Cytoplast Regnetex Titanium 250 (Titanium Ridge Augmentation Mesh
510(k) Number	This Submission	K922489	K051267	K984230	K970841	K972278
Intended Use	The MEDPOR CONTAIN Implant is intended to stabilize, support and provide space maintenance for bone graft materials in the maxilla, mandible, and zygoma.	For augmentation or restoration of bony contour in craniofacial defects.	For use during the process of guided bone regeneration as a bioabsorbable membrane for supporting: augmentation around immediately placed endosseous implants or existing endosseous implants (e.g., dehiscence and fenestration defects, extraction sockets); ridge augmentation for later implantation of endosseous implants; and sinus procedures (e.g., sinus window, sinus lift).	For stabilization and support of bone grafts in dento-alveolar bony defect sites.	For the repair of both localized and extensive alveolar ridge defects, protection for the graft site, membrane support, tissue support.	A temporarily implantable material (non-resorbable) for use as a space-making barrier in the treatment of periodontal defects.
Material	A linear, high-density polyethylene biomaterial	A linear, high-density polyethylene biomaterial	Synthetic resorbable copolymer materials	Grade 1 Titanium	Expanded CP Titanium	A nonporous high density polytetrafluoroethylene film enforced with a titanium framework

Design	15mm x 30mm, 25mm x 30mm, 45mm x 30mm sheets in 0.25mm and 0.35mm thicknesses and other shapes and sizes as well as patient specific customized shapes	Preformed shapes including sheets, micro thin sheets and ultra thin sheets	Regenerative membrane 15mm x 20mm, 20mm x 25mm and 25mm x 30mm	Ti nitride coated perforated mesh 0.009 inch thick 25mm x 30mm, and 12mm x 25mm,	34mm x 25mm 0.10mm thickness	0.25 mm thick 25mm x 30mm, 12mm x 25mm, 14mm x 20mm, 14mm x 24mm, 20mm x 25mm, 13mm x 19mm and 13mm x 18mm
Sterile/ Non-Sterile	Sterile	Sterile	Sterile	Non-Sterile	Sterile	Sterile
Sterilization Method	EtO	EtO	Gamma	Autoclave	Not specified	Steam
Biocompatible	Yes	Yes	Yes	Yes	Yes	Yes

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Jerri L. Mann
Regulatory Compliance Manager
Porex Surgical, Incorporated
15 Dart Road
Newnan, Georgia 30265

MAR 19 2010

Re: K091120
Trade/Device Name: MEDPOR® CONTAIN™ Implant
Regulation Number: 21CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: NPK
Dated: March 11, 2010
Received: March 12, 2010

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices /ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/ default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K091120

Indications for Use

510(k) Number: K091120

Device Name: MEDPOR® CONTAIN™ Implant

Indications for Use: The MEDPOR CONTAIN Implant is intended to stabilize, support and provide space maintenance for bone graft materials in the maxilla, mandible and zygoma.

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 Anesthesiology, General Hospital
Infection Control, Dental Devices

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