K102184

POREX
SURGICAL PRODUCTS GROUP

510(k) Summary

JAN - 7 2011

Date of Summary: July 30, 2010

Manufacturer and Submitter:

Porex Surgical, Inc.
15 Dart Road
Newnan, GA 30265
Tel: (678) 479-1610
Fax: (678) 479-4495

Contact: Stephanie Fullard
E-mail: stephanie.fullard@porex.com

Trade Name: MEDPOR® CONTAIN™ CAN Implant

Descriptive Name: MEDPOR CONTAIN Implant

Classification: II, 21 CFR 872.3930 – Bone grafting material

Product Code: NPK

Predicate Device: MEDPOR CONTAIN Implant (K091120)

Device Description:

The purpose of this Special 510(k) is to add the CAN configuration to MEDPOR CONTAIN Implants. The MEDPOR CONTAIN CAN Implant is a cylinder shaped, thin walled, highly porous, implant that is closed on one end and open on the other. It is made from the same biocompatible pure porous high-density polyethylene (pHDPE) material as MEDPOR CONTAIN Implants in sheet form.

Like the sheet configuration, the CAN is non-resorbable, allows for host integration and is designed to stabilize and support bone graft materials and provide space maintenance necessary for regenerative healing.

The CAN configuration will minimize the need for the surgeon to shape the MEDPOR CONTAIN Sheet Implant, which will reduce the time required for performing the procedure and reduce the possibility of introducing contaminants or debris to the surgical site.

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Indications for Use:

The MEDPOR CONTAIN CAN 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 CAN 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 CAN Implant is designed to minimize the surgeon's need to shape, trim or cut the implant to fit a patient's specific needs. It may be stabilized with tacks, sutures, wires, craniofacial screws or dental implant retention screws. The MEDPOR CONTAIN CAN Implant is manufactured from the same material, packaged, labeled and sterilized the same as all other MEDPOR CONTAIN Implants.

Substantial Equivalence: The MEDPOR CONTAIN CAN Implant is substantially equivalent in intended use, material, function and design principles to the MEDPOR CONTAIN Implant.

– Substantial Equivalence Matrix

	MEDPOR CONTAIN CAN Implant	**Predicate Device MEDPOR CONTAIN Implant**
510(k) Number	This Submission	**K091120**
Device Classification	Class II, Code NPK Reg. No. 872.3930	Class II, Code NPK Reg. No. 872.3930
Intended Use	The MEDPOR CONTAIN CAN Implant is intended to stabilize, support and provide space maintenance for bone graft materials in the maxilla, mandible and zygoma.	The MEDPOR CONTAIN Implant is intended to stabilize, support and provide space maintenance for bone graft materials in the maxilla, mandible and zygoma.
Material	Linear high-density polyethylene biomaterial	Linear high-density polyethylene biomaterial
Shape	Cylinder (Can)	Flat (Sheet)
Diameter (mm)	8, 9, 10	Not Applicable
Thickness (mm)	0.40	0.25, 0.35, 0.45
Sterility	Sterile/Ethylene Oxide	Sterile/Ethylene Oxide
Single Use Only	Yes	Yes
Packaging	Double peel pouch	Double peel pouch
Shelf life	10 years	10 years
Safety & Effectiveness	No changes in function and intended use	

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. Stephanie Fullard
Regulatory Affairs Manager
Porex Surgical, Incorporated
15 Dart Road
Newnan, Georgia 30265

JAN - 7 2011

Re: K102184
Trade/Device Name: MEDPOR® CONTAIN™ CAN Implant
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: NPK
Dated: November 22, 2010
Received: November 24, 2010

Dear Ms. Fullard:

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

Indications for Use

510(k) Number: K102184

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Device Name: MEDPOR® CONTAIN™ CAN Implant

Indications for Use: The MEDPOR CONTAIN CAN 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)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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