K101835

POREX
SURGICAL PRODUCTS GROUP

510(k) SUMMARY

DEC - 3 2010

Date of Summary: September 17, 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® Fixation System – Cranial

Common Name: Plates and Screws

Class: II, 21 CFR 882.5360 – Cranioplasty plate fastener

Product Code: HBW

Substantially equivalent to:

1) Takiron Co., Ltd
OSTEOTRANS™-MX Bioabsorbable Bone Fixation System
K073006

2) Synthes (USA)
Synthes Low Profile Neuro System
K022012

3) Synthes (USA)
Synthes (USA) Craniofacial Plates
K021642

4) Synthes (USA)
SMF Titanium (TI) Alloy Bone Screws
K963546

5) Stryker Leibinger
Stryker Leibinger Universal Neuro System
K031659

K101835

Device Description:

The MEDPOR Fixation System – Cranial is a plate and screw system to be used in Cranial Surgery. The components that comprise the system are composed of titanium plates, titanium alloy bone screws, titanium alloy implant screws, and surgical stainless steel instruments for the installation of the plates and screws. The plates are manufactured of grade 4 titanium and adhere to the American Society of Testing Materials (A.S.T.M.) F67 Standard. The bone and implant screws are manufactured of 6-4 ELI titanium that meets the ASTM F136 standard. The implant screws are designed to be used with MEDPOR polyethylene implants manufactured by Porex Surgical under K832283, K922489, K952677, K040364 and K083621. The screws and plates have been color anodized for ease of use by a surgeon. The blue anodized side of the plate corresponds to the blue anodized bone screw and the magenta anodized side of the plate corresponds to the magenta anodized implant screw. The MEDPOR Fixation System – Cranial is sterilized by ethylene oxide sterilization. The instruments and unused components can be resterilized via steam sterilization.

Indications for Use:

The MEDPOR Fixation System – Cranial is intended for use in cranial surgery to fixate MEDPOR cranial implants to the surrounding cranial skeleton.

Technological Characteristics:

Documentation is provided which demonstrates that the MEDPOR Fixation System – Cranial is substantially equivalent to other legally marketed devices. The technological characteristics of the design are substantially equivalent to the predicate devices and any slight differences do not raise new issues of safety and effectiveness.

Substantial Equivalence:

The following matrix is a comparison of the MEDPOR Fixation System – Cranial to the predicate devices. The MEDPOR Fixation System – Cranial is substantially equivalent in design and intended use to each of the predicate devices. The MEDPOR Fixation System – Cranial is substantially equivalent in material to the predicate devices that are manufactured from titanium. Titanium has a long history of use in surgical implantable products.

K101835

Device	**Proposed Device** MEDPOR Fixation System – Cranial	**Predicate Device #1** OSTEOTRANS – MX Bioabsorbable Bone Fixation System	**Predicate Device #2** Synthes Low Profile Neuro System	**Predicate Device #3** Synthes Craniofacial Plates	**Predicate Device #4** SMF Titanium (TI) Alloy Bone Screws	**Predicate Device #5** Stryker Leibenger Universal Neuro System
510(k) Number	**This Submission**	**K073006**	**K022012**	**K021642**	**K963546**	**K031659**
Device Classification	Class II, Code HBW, Reg. No. 882.5360	Class II, Code GWO, HBW Reg. No. 882.5320, 882.5360	Class II, Code JEY, GXR, DZL Reg. No. 872.4760, 882.5250, 872.4880	Class II, Code JEY Reg. No. 872.4760	Class II, Code DZL Reg. No. 872.4880	Class II, Code JEY Reg. No. 872.4760
Intended Use	The MEDPOR Fixation System – Cranial is intended for use in cranial surgery to fixate MEDPOR cranial implants to the surrounding cranial skeleton.	The OSTEOTRANS – MX Bioabsorbable Bone Fixation System is intended for use in trauma and reconstructive procedures of the craniofacial skeleton, including fracture of the cranium, infant craniofacial surgery (i.e. craniosynotosis, congenital malformations), pediatric reconstructive procedures, reconstructive procedures of the cranium, craniotomy flap fixation.	The Synthes Low Profile Neuro System is intended for use in selective trauma of the midface and craniofacial skeleton; craniofacial surgery; reconstructive procedures; and selective orthognathic surgery of the maxilla and chin.	The Synthes Craniofacial Plates are intended for use in selective trauma of the midface and craniofacial skeleton; craniofacial surgery; reconstructive procedures; and selective orthognathic surgery of the maxilla and chin.	The SMF Ti Alloy Bone Screws are intended for craniofacial and mandibular trauma and reconstruction.	The Stryker Leibinger Universal Neuro System is a low-profile plate and screw system intended for osteotomy, craniotomy, stabilization and rigid fixation of craniofacial fractures and reconstruction of non-load bearing areas.
Materials	*Plates* – CP 4 Titanium *Screws* – 6/4 ELI Titanium Alloy	Bone Plates, Meshes and Screws manufactured from composites of Hydroxyapatite and Poly-L-Lactide (HA/PLLA)	*Plates* – Titanium *Screws* – Ti-6Al-7Nb Titanium Alloy	Titanium	Titanium Alloy	CP Titanium or Ti6Al4V Alloy
Dedicated Instrumentation	Yes	Not Stated	Yes	Yes	Yes	Yes
Sterile/ Nonsterile	Supplied Sterile	Sterile	Nonsterile or Sterile-packed	Nonsterile or Sterile-packed	Nonsterile or Sterile-packed	Nonsterile
Sterilization Methods	Ethylene Oxide & Steam	Not Stated	Steam	Steam	Steam	Steam

K101835

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Porex Surgical, Inc.
C/O Stephanie Fullard
Regulatory Affairs Manager
15 Dart Road
Newnan, GA 30265

DEC - 3 2010

Re: K101835
Trade/Device Name: MEDPOR Fixation System – Cranial
Regulation Number: 21 CFR 882.5360
Regulation Name: Cranioplasty plate fastener
Regulatory Class: Class II
Product Code: HBW
Dated: November 22, 2010
Received: November 23, 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,

Kesia Alexander

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

Enclosure

Indications for Use

DEC - 3 2010

510(k) Number (if known): K101835

Device Name: MEDPOR® Fixation System – Cranial

Indications for Use: The MEDPOR Fixation System – Cranial is intended for use in cranial surgery to fixate MEDPOR cranial implants to the surrounding cranial skeleton.

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, Neurological and Ear, Nose and Throat Devices

510(k) Number K101835