510(K) SUMMARY

Submitted on behalf of:

AUG 8 2012

Company Name:	**OsteoSymbionics, LLC.**
Address:	**1768 East 28th Street** **Cleveland, OH 44114**
Telephone:	**216-881-8500**
Fax:	**216-391-7004**
by:	**Elaine Duncan, M.S.M.E., RAC** **President, Paladin Medical, Inc.** **PO Box 560** **Stillwater, MN 55082**
Telephone:	**715-549-6035**
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CONTACT PERSON:	**Elaine Duncan**

DATE PREPARED:	**July 3, 2012**
TRADE NAME:	**OsteoSymbionics PEEK Patient-Specific Cranial Implant**
COMMON NAME:	**Cranial Plate**
CLASSIFICATION NAME:	**Plate, Cranioplasty, Preformed, Non-Alterable**
PRO CODE:	**GXN**

SUBSTANTIALLY EQUIVALENT TO:

The OsteoSymbionics PEEK Patient Specific Cranial Implants are substantially equivalent to: 1) OsteoSymbionics Patient Specific Cranial Implants made from PMMA (K#072601) and 2) Synthes (USA) Patient Specific Cranial/Craniofacial Implants made from PEEK (K#053199 and K#033868).

Device Characteristics	***OsteoSymbionics PMMA***	***Synthes PEEK***	***OsteoSymbionics PEEK***
Classification Regulation	21 CFR § 882.5330	21 CFR § 882.5330	SAME
Classification Name (Product Code)	Preformed Non-alterable Cranioplasty Plate (GXN)	Synthes (USA) Patient Specific Cranial/Craniofacial Implants (from PEEK) (GXN)	SAME

510(k) Summary-Continued

Device Characteristics	*OsteoSymbionics PMMA*	*Synthes PEEK*	*OsteoSymbionics PEEK*
Device Description	Individually sized and shaped implantable prosthetic cranioplasty plates	Individually sized and shaped implantable prosthetic cranioplasty plates	SAME
Intended Use	To correct defects in craniofacial bone.	To replace bony voids in the cranial/craniofacial skeleton.	SAME
Design	Patient specific	Patient specific	SAME
Attachment Method	Attached to native bone with commercially available cranioplasty fasteners.	Attached to native bone using standard Synthes cranial and craniofacial plates and screws.	SAME

The significant differences between the OsteoSymbionics PEEK Patient Specific Cranial Implant to the predicate made from PMMA is of course, the material PEEK, and the manufacturing methods used to make the PEEK plates compared to the processing of PMMA. The Synthes cranial implants made from PEEK preceded **The OsteoSymbionics PEEK Patient Specific Cranial Implants,** as have other PEEK cranial plates (not listed herein as predicates.)

DESCRIPTION of the DEVICE:

OsteoSymbionics Patient-Specific Cranial Implant (PEEK), manufactured by OsteoSymbionics, LLC, is a prosthetic cranioplasty implant. Each implant is sized and shaped from one or more pieces to fit the specific patient's cranial skeleton. The devices are manufactured from **PEEK** and provided non-sterile for sterilization prior to implantation. Implantable prosthetic cranioplasty implants are intended to fill a specific patient's defect, so each device is manufactured one at a time to custom-order based upon the patient's CT scan. The device can be crafted to include perfusion holes (2mm in diameter, spaced 10mm apart) upon surgeon preference (on order sheet). The implants are attached to the native bone with commercially available cranioplasty fasteners.

INTENDED USE: OsteoSymbionics PEEK Patient-Specific Cranial Implants are designed individually for each patient to correct defects in cranial bone.

510(k) Summary-Continued

INDICATIONS FOR USE:

OsteoSymbionics PEEK Patient-Specific Cranial Implants are designed individually for each patient to correct defects in cranial bone.

SUMMARY of Testing and Basis for Substantial Equivalence:

OsteoSymbionics PEEK Patient-Specific Cranial Implants are manufactured from PEEK and provided non-sterile for sterilization prior to implantation. The sterilization instructions on the instruction for use have been validated.

The PEEK materials are shown to be biocompatible and that manufacturing processes due not introduce risk of contamination.

The software used to facilitate the difference in manufacturing process between the original PMMA device and the PEEK device made by OsteoSymbionics has been validated.

Mechanical testing has shown the PEEK implant to be comparable to the PMMA implant made by OsteoSymbionics.

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

AUG 8 2012

OsteoSymbionics, LLC.
c/o Ms. Elaine Duncan
President, Paladin Medical, Inc.
PO Box 560
Stillwater, MN 55082

Re: K121102
Trade/Device Name: OsteoSymbionics PK Shield (PEEK Patient-Specific Cranial Implant)
Regulation Number: 21 CFR 882.5330
Regulation Name: Preformed nonalterable cranioplasty plate
Regulatory Class: Class II
Product Code: GXN
Dated: July 27, 2012
Received: July 30, 2012

Dear Ms. Duncan:

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 Jessia Alexander

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

K121102

Indications for Use

510(k) Number (if known): K121102

Device Name:

OsteoSymbionics PK Shield (PEEK Patient Specific Cranial Implant)

Indications for Use:

OsteoSymbionics PK Shield (PEEK Patient Specific Cranial Implant) is designed individually for each patient to correct defects in cranial bone.

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

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF 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 K121102