K072601 page 1 of 1

osteo symbionics™

510(k) Summary of Safety and Effectiveness

(as required by 21 CFR § 807.92)

DEC 1 0 2007

510(k) Submitter	OsteoSymbionics, LLC 1768 East 25th Street Cleveland, Ohio 44114
Contact Person	Ms. Cynthia Brogan, President *Phone:* (216) 881-8500 *e-mail:* cb@osteosymbionics.com
Date Prepared	September 12, 2007
Device Name	*Proprietary Name:* OsteoSymbionics Patient-Specific Cranial Implant *Common Name:* patient-specific cranial implant *Classification Name:* "plate, cranioplasty, preformed, non-alterable," a class II device in accordance with 21 CFR § 882.5330
Device Description	The OsteoSymbionics Patient Specific Cranial Implants are individually sized and shaped implantable prosthetic cranioplasty plates intended to fill defects in a specific patient's cranial/craniofacial skeleton. The implants are composed of polymethyl methacrylate and are fabricated using the patient's CT imaging data. The devices are provided non-sterile for sterilization prior to implantation and are attached to the native bone with commercially available cranioplasty fasteners.
Indication for Use	The OsteoSymbionics Patient-Specific Cranial Implants are designed individually for each patient to correct defects in craniofacial bone.
Substantial Equivalence	The OsteoSymbionics Patient-Specific Cranial Implants are substantially equivalent in terms of safety and effectiveness to the following legally marketed devices: Synthes Patient Specific Cranial/Craniofacial Implants - K033868 Synthes (USA) Stryker® Patient Specific Polymer Implant - K043250 Stryker Liebinger Codman Cranioplastic - K873689 Codman Division of Johnson & Johnson

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 0 2007

OsteoSymbionics, LLC
% Ms. Cynthia Brogan
President
1768 East 25th Street
Cleveland, OH 44114

Re: K072601
Trade/Device Name: OsteoSymbionics Patient-Specific Cranial Implant
Regulation Number: 21 CFR 882.5300
Regulation Name: Methyl methacrylate for cranioplasty
Regulatory Class: Class II
Product Code: GXP, GXN
Dated: September 12, 2007
Received: September 14, 2007

Dear Ms. Brogan:

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) 276-0120. 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,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K072601

Device Name: OsteoSymbionics Patient-Specific Cranial Implants

Indications for Use: The OsteoSymbionics Patient Specific Cranial Implants are designed individually for each patient to correct defects in craniofacial bone.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use No (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 General, Restorative, and Neurological Devices

510(k) Number K072601