SYNTHES®

DEC 1 4 2005

K053199

3.0 510(k) Summary

Sponsor:

Synthes (USA)
1302 Wrights Lane East
West Chester, PA 19380
(610) 719-5000

Device Name: Synthes Patient Specific Cranial/Craniofacial Implant (PSCI)

Classification: Class II § 21 CFR 882.5330: Plate, Cranioplasty, preformed, non-alterable

Predicate Devices:

- Synthes Patient Specific Cranial/Craniofacial Implant, K033868
- Porex Medical: MEDPOR Porous Polyethylene Cranial Implants, K832283

Device Description: The Synthes Patient Specific Cranial/Craniofacial Implant (PSCI) replaces bony voids in the cranial/craniofacial skeleton. Multi-piece implants are preformed / pre-shaped to fit the anatomy of the patient, will range in size from 100 x 100 mm to 350 x 350 mm, and attach to the native bone using standard Synthes cranial and craniofacial plates and screws in sizes 1.3 mm through 2.0 mm. The Synthes Patient Specific Cranial/Craniofacial Implants are manufactured from CP Titanium and PEEK.

Intended Use: Synthes (USA) Patient Specific Cranial/Craniofacial Implant is intended to replace bony voids in the cranial/craniofacial skeleton.

Substantial Equivalence: Information presented supports substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 14 2005

Ms. Kathleen Anderson
Regulatory Affairs Manager
Synthes (USA)
1302 Wrights Lane East
West Chester, Pennsylvania 19380

Re: K053199
Trade/Device Name: Synthes Patient Specific Cranial/Craniofacial Implant (PSCI)
Regulation Number: 21 CFR 882.5330
Regulation Name: Preformed nonalterable cranioplasty plate
Regulatory Class: Class II
Product Code: GXN
Dated: November 15, 2005
Received: November 16, 2005

Dear Ms. Anderson:

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 Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

SYNTHES®

2.0 **Indications for Use**

510(k) Number (if known): K053199

Device Name: Synthes (USA) Patient Specific Cranial/Craniofacial Implant

Indications for Use:

Synthes (USA) Patient Specific Cranial/Craniofacial Implant is intended to replace bony voids in the cranial and/or craniofacial skeleton.

Prescription Use X AND/OR Over-The-Counter Use
(Per 21 CFR 801.109) (21 CFR 807 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 K053199