

JUN 21 2004

K033868  
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**Summary of Safety and Effectiveness Information [510(k) Summary]**

**SPONSOR:** Synthes (USA)  
1690 Russell Road  
Paoli, PA 19301  
(610) 647-9700  
Contact: Lisa M. Boyle

**DEVICE NAME:** Synthes (USA) Patient Specific Cranial/Craniofacial Implants

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

**PREDICATE DEVICE:** • Porex Medical: MEDPOR Porous Polyethylene Cranial Implants

**DEVICE DESCRIPTION:** The Synthes Patient Specific Cranial/Craniofacial Implant replaces bony voids in the cranial/craniofacial skeleton. The implants are preformed / pre-shaped to fit the anatomy of the patient, will range in size from 10 x 10 mm to 200 x 200 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:** Comparative information presented supports substantial equivalence.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUN 21 2004

Ms. Lisa M. Boyle  
Regulatory Associate  
Synthes (USA)  
1690 Russel Road  
Paoli, PA 19301

Re: K033868

Trade/Device Name: Synthes (USA) Patient Specific Cranial/Craniofacial Implants  
Regulation Number: 21 CFR 882.5330  
Regulation Name: Plate, cranioplasty, preformed, non-alterable  
Regulatory Class: Class II  
Product Code: GXN  
Dated: December 11, 2003  
Received: December 12, 2003

Dear Ms. Boyle:

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.

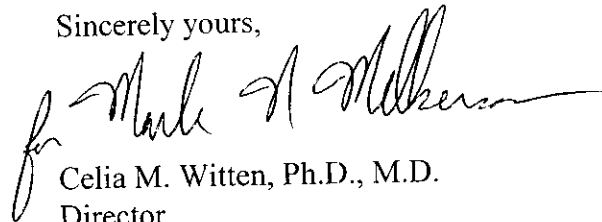
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

Page 2 – Ms. Lisa M. Boyle

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 (301) 594-4659. 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/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "for Celia M. Witten". The signature is written in a cursive style and is positioned to the left of the typed name.

Celia M. Witten, Ph.D., M.D.  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**Indications for Use Statement**

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510(k) Number (if known): K033868

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

**Indications:**

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X  
(Per 21 CFR 801.109)

OR Over-The-Counter Use  
*for* Mark A. Milbrink  
**(Division Sign-Off)**  
**Division of General, Restorative,  
and Neurological Devices**

510(k) Number K033868