K041350

SYNTHES®

JUL - 8 2004

3.0 510(k) Summary

Sponsor:

Synthes (USA)
1690 Russell Road
Paoli, PA 19301
(610) 647-9700

Device Name:

Synthes (USA) chronOS™

Classification:

Class II, 21 CFR §882.5300
Methylmethacrylate for Cranioplasty

Class II, 21 CFR §880.5600
Piston Syringe

Predicate Device:

Norian Cranial Repair System (CRS) Bone Cement
Etex α-BSM™ Bone Substitute Material for Cranioplasty

Device Description:

Synthes chronOS is a porous, osteoconductive, resorbable bone void filler made from ß-Tricalcium Phosphate (TCP). chronOS features a uniform three dimensional pore structure. Pore diameters within the material range from 100 to 500 µm. chronOS is provided sterile in granules and preformed shapes (e.g. blocks, cylinders, wedges).

chronOS may be packaged with a perfusion syringe that is used to mix the bone void filler with the patient's blood components.

Intended Use:

Synthes chronOS is intended for the repair or filling of craniofacial defects and craniotomy cuts with a surface area no larger than 25 cm^2. It is also indicated for the restoration or augmentation of bony contours of the craniofacial skeleton, including the fronto-orbital, malar and mental areas.

Synthes chronOS is intended to be gently packed or placed into the site. chronOS resorbs and is replaced with bone during the healing process.

Substantial Equivalence:

Documentation is provided which demonstrates that Synthes chronOS is substantially equivalent* to other legally marketed Synthes devices.

*The term "substantial equivalence" as used in the 510(k) notification is limited to the definition of substantial equivalence found in the Food, Drug and Cosmetic Act, as amended and as applied under 21 CRF 807, Subpart E, under which a device can be marketed without pre-market approval or reclassification;. A determination of substantial equivalency under this notification is

not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 8 2004

Ms. Sheri L. Musgnung
Regulatory Affairs Specialist
Synthes(USA).
1690 Russell Road
Paoli, PA 19301

Re: K041350
Synthes chronOS™ and Perfusion Syringe
Regulation Number: 21 CFR 882.5300, 880.5860
Regulation Name: Methy Methacrylate for Cranioplasty and Piston Syringe
Regulatory Class: Class II
Product Code: GXP, FMF
Dated: May 19, 2004
Received: May 20, 2004

Dear Ms. Musgnung:

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 (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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,

Miriam C. Provost

for 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

SYNTHES®

Indications for Use

510(k) Number (if known):

Device Name: Synthes (USA) chronOS™

Indications: Synthes chronOS is intended for the repair or filling of craniofacial defects and craniotomy cuts with a surface area no larger than 25 cm^2. It is also indicated for the restoration or augmentation of bony contours of the craniofacial skeleton, including the fronto-orbital, malar and mental areas.

Synthes chronOS is intended to be gently packed or placed into the site. chronOS resorbs and is replaced with bone during the healing process.

Prescription Use ✓ AND/OR Over-The-Counter Use_____
(Per 21 CFR 801 Subpart D) (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)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K041350