SYNTHES®

MAR 4 - 2005

K050204

3.0 **510(k) Summary**

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

Device Name:
Synthes Rapid Resorbable Tack System

Classification:
Class II, 21 CFR §882.5360
Cranioplasty plate fastener

Predicate Device:
Synthes Resorbable Tack System
Synthes Rapid Resorbable Fixation System (aka Synthes Poly (L-Lactide-co-Glycolide) Resorbable Fixation System

Device Description:
The Synthes Rapid Resorbable Tack System consists of resorbable tacks and accessory instruments, which are additional components of the Synthes Rapid Resorbable Fixation System. The Rapid Resorbable Tack System consists of 1.5 mm tacks and 1.7 mm emergency tacks and are available in lengths ranging from 4 – 6 mm.

Intended Use:
Synthes Rapid Resorbable Tack System is intended for use in fracture repair and reconstructive procedures of the craniofacial skeleton. In addition, Rapid Resorbable Tacks may be used in non-load bearing applications for maintaining the relative position of and/or containing bony fragments, bone grafts (autograft or allograft) or bone graft substitutes in reconstruction of the craniofacial or mandibular areas.

Contraindications:
These devices are not intended for use in load bearing applications, such as the mandible, unless used in conjunction with traditional rigid fixation. Synthes Rapid Resorbable Tacks are not intended for areas with active or latent infection or for patient conditions including limited blood supply or insufficient quantity or quality of bone. These devices are not intended for use in the spine.

Substantial Equivalence:
Documentation is provided which demonstrates that Synthes Rapid Resorbable Tack System is substantially equivalent to other legally marketed Synthes devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 4 - 2005

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

Re: K050204
Trade/Device Name: Synthes Rapid Resorbable Tack System
Regulation Number: 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: JEY
Dated: March 2, 2005
Received: March 3, 2005

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 (240) 276-0115. 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/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SYNTHES®

Indications for Use

510(k) Number (if known): K050204

Device Name: Synthes Rapid Resorbable Tack System

Indications: Synthes Rapid Resorbable Tack System is intended for use in fracture repair and reconstructive procedures of the craniofacial skeleton. In addition, Rapid Resorbable Tacks may be used in non-load bearing applications for maintaining the relative position of and/or containing bony fragments, bone grafts (autograft or allograft) or bone graft substitutes in reconstruction of the craniofacial or mandibular areas.

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Prescription Use ___X___ 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)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

(510(k) Number K050204