SYNTHES®

MAY 1 8 2005

K050608

3.0 510(k) Summary

Sponsor:

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

Device Name: Synthes (USA) Craniofacial Plate and Screw System

Classification: Class II, 21 CFR §872.4760
Bone plate

Class II, 21 CFR §872.4880
Intraosseous fixation screw or wire

Predicate Device:
Synthes Midfacial System
Synthes Orbital Mesh Plates F/Synthes Midfacial System
Synthes Maxillofacial Titanium Micro Set
Synthes Cranial Plates
Synthes 1.5 mm Self-tapping cortex screws

Device Description: Synthes Craniofacial Plate and Screw System consist of plates and meshes that come in a variety of shapes and sizes to meet the anatomical needs of the patient. This system is designed for use with 1.8 mm screws and 2.1 mm emergency screws. The screws will be used with Synthes 1.8 mm hexagonal screwdriver blades. System components are manufactured in either titanium or titanium alloy and are intended for single use only.

Intended Use: Synthes Craniofacial Plate and Screw System is intended for use in selective trauma of the midface and craniofacial skeleton; craniofacial surgery; reconstructive procedures; and selective orthognathic surgery of the maxilla and chin.

Substantial Equivalence: Documentation is provided which demonstrates that the Synthes Craniofacial Plate and Screw System is substantially equivalent to other legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 18 2005

Ms. Sheri L. Musgnung
Senior Regulatory Affairs Specialist
Synthes (USA)
1302 Wrights Lane East
West Chester, Pennsylvania 19380

Re: K050608
Trade/Device Name: Synthes (USA) Craniofacial Plate and Screw Systems
Regulation Number: 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: JEY, DZL
Dated: March 9, 2005
Received: March 10, 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): K050608

Device Name: Synthes (USA) Craniofacial Plate and Screw System

Indications: Synthes Craniofacial Plate and Screw System is intended for use in selective trauma of the midface and craniofacial skeleton; craniofacial surgery; reconstructive procedures; and selective orthognathic surgery of the maxilla and chin.

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)

Susan Runner

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

510(k) Number: K050608