MAR 1 2 2009

K083388

3.0 510(k) Summary

Sponsor:

Synthes (USA)
1301 Goshen parkway
West Chester, PA 19380

Contact: Andrea M. Tasker
(610) 719-6290

Device Name: Synthes MatrixORTHOGNATHIC Plating System

Classification: Class II; 21 CFR §872.4760, Bone plate

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

Predicate Device:
Synthes Craniofacial Plates
Synthes Craniofacial Plate and Screw System
Synthes 1.5mm/2.0mm Orthognathic Maxillary Plates
Synthes SMF Titanium Alloy Bone Screws
Xsorb™ Bioabsorbable Craniofacial Fixation System

Device Description: The Synthes MatrixORTHOGNATHIC Plating System consists of a variety of plates that come in a variety of shapes and sizes to meet the anatomical needs of the patient. This system is designed for use with Synthes Matrix screws. System components are manufactured in either titanium or titanium alloy and are intended for single use only.

Intended Use: The Synthes MatrixORTHOGNATHIC Plating 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, mandible and chin in adolescents (greater than 12 to 21 years of age) and adults.

Specific Indications for Use:

- Fractures of the midface and craniofacial skeleton
- LeFort I osteotomies, sagittal split osteotomies and genioplasties
- Orthognathic surgery including reconstructive procedures

Substantial Equivalence: Documentation is provided in this submission which demonstrates that the Synthes MatrixORTHOGNATHIC Plating 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

MAR 1 2 2009

Ms. Andrea M. Tasker
Synthes (USA)
1301 Goshen Parkway
West Chester, Pennsylvania 19380

Re: K083388
Trade/Device Name: Synthes MatrixORTHOGNATHIC Plating System
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: JEY
Dated: January 14, 2009
Received: January 14, 2009

Dear Ms. Tasker:

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.

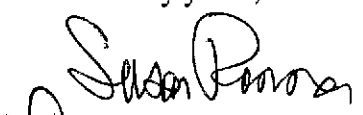
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Ginette Y. Michaud, M.D.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K08 3388

Device Name: Synthes MatrixORTHOGNATHIC Plating System

Indications:

The Synthes MatrixORTHOGNATHIC Plating 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, mandible and chin in adolescents (greater than 12 to 21 years of age) and adults.

Specific Indications for Use:

- Fractures of the midface and craniofacial skeleton
- LeFort I osteotomies, sagittal split osteotomies and genioplasties
- Orthognathic surgery including reconstructive procedures

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: K083388