K063790

3.0 510(k) Summary

Sponsor: Synthes (USA)
1301 Goshen Parkway
West Chester, PA 19380
(610) 719-5000

APR 16 2007

Contact: Deborah L Jackson, RAC
Synthes (USA)
1301 Goshen Parkway
West Chester, PA 19380
(610) 719-6948

Device Name: The Synthes MatrixMANDIBLE Plate and Screw System

Classification: 21 CFR 872.4760: Bone plate

Predicate Devices: Synthes 2.4 mm Universal Locking Plate System
Synthes 2.0 Locking Plate System
Synthes Mandibular Modular Fixation System
Stryker Leibinger NewGen System

Device Description: The Synthes MatrixMANDIBLE Plate and Screw System is the next generation of Synthes (USA) fixation systems for the mandible. The system incorporates small, medium, and large plates designed so that all plates accept all system screws. The plates are available in various shapes and thicknesses, and accept self-tapping cortex and locking screws. The implants are manufactured from CP titanium and titanium alloy.

Intended Use: The Synthes MatrixMANDIBLE Plate and Screw System is intended for oral, maxillofacial surgery; trauma; reconstructive surgery; and orthognathic surgery (surgical correction of dentofacial deformities).

Substantial Equivalence: Information presented supports substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Deborah L. Jackson
Regulatory Affairs Specialist
Synthes (USA)
1301 Goshen Parkway
West Chester, Pennsylvania 19380

APR 16 2007

Re: K063790
Trade/Device Name: The Synthes MatrixMANDIBLE Plate and Screw System
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: JEY
Dated: March 30, 2007
Received: April 2, 2007

Dear Ms. Jackson:

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.

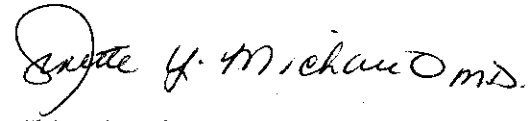
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-3150 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®

2.0 Indications for Use

510(k) Number (if known): K063790

Device Name: The Synthes MatrixMANDIBLE Plate and Screw System

Indications for Use: The Synthes MatrixMANDIBLE Plate and Screw System is intended for oral, maxillofacial surgery; trauma; reconstructive surgery; and orthognathic surgery (surgical correction of dentofacial deformities).

Prescription Use X AND/OR Over-The-Counter Use
(Per 21 CFR 801.109) (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 of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K063790