SYNTHES®

DEC 11 2009

K091233

3.0 510(k) Summary

Sponsor: Synthes
1301 Goshen Parkway
West Chester, PA 19380

Contact: Contact: Andrea M. Tasker
tasker.andrea@synthes.com
(610) 719-6290

Device Name: Synthes MatrixMANDIBLE Subcondylar Plates

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

Predicate Devices: Synthes MatrixMANDIBLE Plate and Screw System
MODUS® Titanium Osteosynthesis System

Device Description: The Synthes MatrixMANDIBLE Subcondylar Plates are designed specifically to match the anatomy of the subcondylar region of the mandible. These plates are designed for use with Synthes MatrixMANDIBLE screws that come in multiple diameters and lengths to meet the anatomical needs of the patient. System components are manufactured in either titanium or titanium alloy and are intended for single use only.

Intended Use: The Synthes MatrixMANDIBLE Subcondylar Plates are intended for oral, maxillofacial surgery; trauma and reconstructive surgery, specifically for fractures of the subcondylar region of the mandible and fractures of the condylar basis region of the mandible.

Substantial Equivalence: Information presented supports substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

DEC 11 2009

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

Re: K091233
Trade/Device Name: Synthes MatrixMANDIBLE Subcondylar Plates
Regulation Number: 21CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: JEY
Dated: November 23, 2009
Received: November 25, 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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, BS, MS, MBA
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): K091233

Device Name: Synthes MatrixMANDIBLE Subcondylar Plates

INDICATIONS FOR USE:

The Synthes MatrixMANDIBLE Subcondylar Plates are intended for oral, maxillofacial surgery; trauma and reconstructive surgery, specifically for fractures of the subcondylar region of the mandible and fractures of the condylar basis region of the mandible.

Prescription Use ___X___ (Per 21 CFR 801.109) AND/OR Over-The-Counter Use_____ (21 CFR 807 Subpart C)

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

510(k) Number: K091233