AUG 2 5 2009

SYNTHES®

K091144

3.0 510(k) Summary

Sponsor:	Synthes 1301 Goshen Parkway West Chester, PA 19380 (610) 719-6604
Contact:	Amnon Talmor Synthes 1301 Goshen Parkway West Chester, PA 19380 (610) 719-6604
Device Name:	Synthes MatrixMANDIBLE Preformed Reconstruction Plates
Classification:	Class II per 21 CFR §872.4760: Plate, Bone
Predicate Devices:	Synthes MatrixMANDIBLE Plate and Screw System
Device Description:	The subject of this 510(k) is the Synthes MatrixMANDIBLE Preformed Reconstruction Plates. These plates are anatomically contoured to match the body and angle regions of the mandible in most patients. 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 Preformed Reconstruction Plates are intended for use in oral and maxillofacial surgery, trauma and reconstructive surgery. This includes primary mandibular reconstruction, comminuted fractures and temporary bridging pending delayed secondary reconstruction, including fractures of edentulous and/or atrophic mandibles, as well as unstable fractures.
Substantial Equivalence:	Information presented supports substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

AUG 2 5 2009

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

Re: K091144
Trade/Device Name: Synthes MatrixMANDIBLE Preformed Reconstruction Plates
Regulation Number: 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: JEY
Dated: August 12, 2009
Received: August 13, 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,

for

Susan Runner, D.D.S., M.A.
Acting 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): K091144

Device Name: Synthes MatrixMANDIBLE Preformed Reconstruction Plates

Indications for Use: The Synthes MatrixMANDIBLE Preformed Reconstruction Plates are intended for use in oral and maxillofacial surgery, trauma and reconstructive surgery. This includes primary mandibular reconstruction, comminuted fractures and temporary bridging pending delayed secondary reconstruction, including fractures of edentulous and/or atrophic mandibles, as well as unstable fractures.

Prescription Use X (Per 21 CFR 801.109) AND/OR Over-The-Counter Use_____ (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)

Ron Mulley for MSR

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

510(k) Number: K091144