

**3.0 510(k) Summary**Page   1   of   1  

**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.



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

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

DEC 11 2009

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.

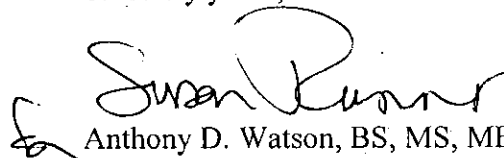
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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other 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



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