K080109 (pg 1/1)

MAR 20 2008

3.0 510(k) Summary

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

Contact:
Jill R. Sherman
Synthes (USA)
1301 Goshen Parkway
West Chester, PA 19380
610-719-6538

Device Name: Synthes (USA) Modular Blade Plate System

Classification: 21 CFR Part 888.3030; Single/multiple component metallic bone fixation appliances and accessories.

Predicate Device: Synthes Angled Blade Plates (Pre-amendment and K914546)

Device Description: The Synthes (USA) Modular Blade Plate System is comprised of a spiral blade that attaches to one end of a side plate, secured with a coupling screw to create a fixed angle construct. The Modular Plates are available in various configurations - 90°, 110°, 120° and 130° plates with off-sets, and 95° or 130° plates without off-sets. The Modular Plates have standard locking-compression holes (LCP) in the shaft and are available in a variety of lengths to accommodate varying injury, patient anatomy and size. The Modular Plates are available to be used with 4.5 mm Cortex screws or 5.0 mm Locking screws. The Spiral Blades rotate 90° clockwise or counterclockwise over the length of the blade. A variety of lengths are available to accommodate varying patient anatomy. The coupling screw is one size fits all plate and blade configurations.

Intended Use: The Synthes (USA) Modular Blade Plate System is indicated for fixation of fractures and osteotomies of the proximal and distal femur in adolescents and adults.

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

Synthes (USA)
% Ms. Jill R. Sherman
1301 Goshen Parkway
West Chester, PA 19380

MAR 20 2008

Re: K080109
Trade/Device Name: Synthes (USA) Modular Blade Plate System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: KTW
Dated: January 11, 2008
Received: January 15, 2008

Dear Ms. Sherman:

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) 276-0120. 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 toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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SYNTHES®

2.0 **Indications for Use**

510(k) Number (if known): _____

Device Name: Synthes (USA) Modular Blade Plate System

Indications for Use: The Synthes (USA) Modular Blade Plate System is indicated for fixation of fractures and osteotomies of the proximal and distal femur in adolescents and adults.

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)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K080109