SYNTHES®

K080943

510(k) Summary

APR 23 2008

Sponsor: Synthes (USA)
1301 Goshen Parkway
West Chester, PA 19380
(610) 719-6940

Contact: Sheri L. Musgnung
Synthes (USA)
1301 Goshen Parkway
West Chester, PA 19380
(610) 719-6940
FAX (610) 484-356-9682

Device Name: Synthes 4.5 mm and 6.5 mm Headless Compression Screws

Classification: Class II, §888.3040 – Smooth or threaded metallic bone fixation fastener.

Predicate Device: Synthes 4.5 mm Cannulated Screws
Synthes 6.5 mm Cannulated Screws
OsteoMed's Headless Cannulated Screw System

Device Description: Synthes 4.5 mm and 6.5 mm Headless Compression Screws are cannulated and are self-drilling/self tapping, feature a StarDrive recess, and have a threaded head which can be countersunk into the bone. They are available in stainless steel and titanium alloy, in a variety of lengths.

Intended Use: The Synthes 4.5 mm and 6.5 mm Headless Compression Screws are indicated for fracture fixation, reconstruction, osteotomy, and arthrodesis of various bones and bone fragments including joint fusions (arthrodeses) in the foot and fixation of intra-articular fractures of the humerus, femur and tibia.

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

APR 23 2008

Synthes (USA)
% Ms. Sheri Musgnung
1301 Goshen Parkway
West Chester, PA 19380

Re: K080943
Trade/Device Name: Synthes 4.5 mm and 6.5 mm Headless Compression Screws
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: April 2, 2008
Received: April 3, 2008

Dear Ms. Musgnung:

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

SYNTHES®

Indications for Use

510(k) Number (if known): K080943

Device Name: Synthes 4.5 mm and 6.5 mm Headless Compression Screws

Indications for Use:

The Synthes 4.5 mm and 6.5 mm Headless Compression Screws are indicated for fracture fixation, reconstruction, osteotomy, and arthrodesis of various bones and bone fragments including joint fusions (arthrodeses) in the foot and fixation of intra-articular fractures of the humerus, femur and tibia.

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)

Neil R Ogden for rxn

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

510(k) Number K080943