K111230

Attachment 1: Revised 510(k) Summary

MAY 2 4 2011

Sponsor:

Synthes (USA)
Rebecca Blank
Associate Regulatory Affairs Specialist
1301 Goshen Parkway
West Chester, PA 19380
(610) 719-1268
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Date Prepared: April 29, 2011

Device Name: Synthes 3.5mm Low Profile Cortical Screw

Classification: Class II, § 888.3040 - Smooth or Threaded Metallic Bone Fixation Fastener
Product Code: HWC

Predicate Device(s): Synthes 3.5mm Cortex Screws **(K043185)**

Device Description: The 3.5mm Low Profile Cortical Screws are self-tapping, have either a stardrive or hexdrive recess, are manufactured from stainless steel and titanium and offered both sterile and non sterile. The self-tapping screws are available in lengths ranging from 10mm - 110mm and may be used independently or with any Synthes plate which accepts Synthes 3.5mm cortical screws. The low profile screw head is designed to minimize hardware prominence and the resultant potential for soft tissue irritation.

Intended Use: The Synthes 3.5mm Low Profile Cortical Screws are intended for fixation of fractures, osteotomies, and non-unions of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, tibia, calcaneous, femur, and fibula in adults, and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by the screw fixation.

Substantial Equivalence: Information presented supports substantial equivalence of the Synthes 3.5mm Low Profile Cortical Screw to the predicate devices. The proposed low profile screw has similar indications for use, is similar in design, incorporates the same fundamental product technology and is composed of the same materials.

To additionally support substantial equivalence, geometric cross sectional analysis was conducted to compare the subject device to the predicate device with results supporting substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Synthes (USA)
% Ms. Rebecca Blank
Associate Regulatory Affairs Specialist
1301 Goshen Parkway
West Chester, Pennsylvania 19380

MAY 24 2011

Re: K111230
Trade/Device Name: Synthes (USA) 3.5 mm Low Profile Cortical Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: April 29, 2011
Received: May 2, 2011

Dear Ms. Blank:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

Enclosure

Attachment 2: Revised Indications for Use

510(k) Number (if known): K111230

Device Name: Synthes (USA) 3.5mm Low Profile Cortical Screw

Indications for Use:

The Synthes 3.5mm Low Profile Cortical Screws are intended for fixation of fractures, osteotomies, and non-unions of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, tibia, calcaneous, femur, and fibula in adults, and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by the screw fixation.

Prescription Use ___X___ (Per 21 CFR 801.109) AND/OR Over-The-Counter Use_____ (21 CFR 801 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 Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111230