K070294

SYNTHES®

MAR 0 1 2007

3.0 510(k) Summary

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

Device Name: Synthes Trochanteric Fixation Nail (TFN) System, additional Helical Blades

Classification: 21 CFR 888.3020: Rod, Fixation, Intramedullary and Accessories

Predicate Devices: Synthes Trochanteric Fixation Nail (TFN) System

Device Description: Synthes TFN System consists of a cannulated femoral nail, a cannulated helical blade and a cannulated nail end cap. Synthes Helical Blades will be available in three additional lengths, 75 mm, 125 mm, and 130 mm.

Intended Use: Synthes Trochanteric Fixation Nail (TFN) System is intended to treat stable and unstable fractures of the proximal femur including pertrochanteric fractures, intertrochanteric fractures, basal neck fractures, and combinations thereof. The Long TFN is additionally indicated for subtrochanteric fractures, pertrochanteric fractures associated with shaft fractures, pathologic fractures (including prophylactic use) in both trochanteric and diaphyseal regions, long subtrochanteric fractures, proximal or distal non-unions, malunions, and revisions.

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. Sheri L. Musgnung
Senior Regulatory Affairs Specialist
1301 Goshen Parkway
West Chester, Pennsylvania 19380

MAR 0 1 2007

Re: K070294
Trade/Device Name: Synthes Trochanteric Fixation Nail (TFN) system, additional helical blades
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB, HWC
Dated: January 30, 2007
Received: January 31, 2007

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.

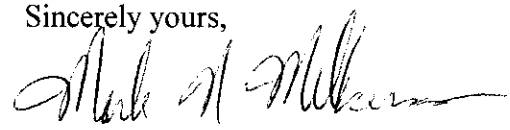
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). 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 240-276-3150 or at its 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®

2.0 **Indications for Use**

510(k) Number (if known): K070294

Device Name: Synthes Trochanteric Fixation Nail (TFN) System, Additional Helical Blades

Indications for Use: Synthes Trochanteric Fixation Nail (TFN) System is intended to treat stable and unstable fractures of the proximal femur including pertrochanteric fractures, intertrochanteric fractures, basal neck fractures, and combinations thereof. The Long TFN is additionally indicated for subtrochanteric fractures, pertrochanteric fractures associated with shaft fractures, pathologic fractures (including prophylactic use) in both trochanteric and diaphyseal regions, long subtrochanteric fractures, proximal or distal non-unions, malunions, and revisions.

Mark A Miller

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

510(k) Number K070294

Prescription Use X AND/OR Over-The-Counter Use No
(Per 21 CFR 801.109) (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)