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SYNTHES®

3.0 510(k) Summary

APR - 8 2010

Sponsor: Synthes (USA)
1301 Goshen Parkway
West Chester, PA 19380
(610) 719-6604

Contact: Karl J. Nittinger
Synthes (USA)
1301 Goshen Parkway
West Chester, PA 19380
(610) 719-6941

Device Name: Synthes (USA) TomoFix™ Medial High Tibia Plate, Small

Classification: Class II, §888.3030 – Single / multiple component metallic bone fixation appliance and accessories.

Classification Product Code: HRS (Plate, Fixation, Bone)

Predicate Devices: Synthes (USA) TomoFix™ Osteotomy System

Device Description: The Synthes (USA) TomoFix™ Medial High Tibia Plate is a part of the Synthes TomoFix™ Osteotomy System which is a system consisting of titanium plates with locking and combination holes designed to provide stable fixation close to the knee.

Indications for Use: The Synthes (USA) TomoFix™ Osteotomy System is intended for open and closed wedge osteotomies of the medial proximal tibia, lateral proximal tibia, medial and lateral distal femur, treatment of bone and joint deformities, fractures, and malalignment caused by injury or disease such as osteoarthritis. .

Substantial Equivalence: Information presented supports the substantial equivalence of the TomoFix Medial High Tibia Plate, Small to the predicate device. The proposed plate has the same indications for use, is similar in shape/design, incorporates the same fundamental product technology and is composed of the same materials. Additionally, preclinical testing – including dynamic fatigue and static 3-point bend testing - was performed comparing the proposed plate to the predicate plate and the results support 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

APR - 8 2010

Synthes (USA)
% Karl J. Nittinger
1301 Goshen Parkway
West Chester, PA 19380

Re: K100676
Trade/Device Name: Synthes (USA) TomoFix™ Medial High Tibia Plate, Small
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliance and accessories
Regulatory Class: Class II
Product Code: HRS
Dated: February 18, 2010
Received: March 10, 2010

Dear Mr. Nittinger:

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,

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

Enclosure

SYNTHES®

2.0 **Indications for Use**

510(k) Number (if known): K100676 (pg 1/1)

Device Name: Synthes (USA) TomoFix™ Medial High Tibia Plate, Small

Indications for Use: The Synthes TomoFix™ Osteotomy System is intended for open and closed wedge osteotomies of the medial proximal tibia, lateral proximal tibia, medial and lateral distal femur, treatment of bone and joint deformities, fractures, and malalignment caused by injury or disease such as osteoarthritis.

Prescription Use ____X____ AND/OR Over-The-Counter Use_____
(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)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100676