



K092812

3.0 510(k) Summary

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- Date Prepared:** May 5, 2010
- Sponsor:** Synthes (USA)
Karl J. Nittinger
1301 Goshen Parkway
West Chester, PA 19380
(610) 719-6941
- Device Name:** Synthes (USA) 2.7mm / 3.5mm LCP Anterolateral Distal Tibia Plates
- Classification:** Class II, §888.3030 – Single / multiple component metallic bone fixation appliance and accessories.
- Predicate Device:** Synthes 3.5mm LCP Distal Tibia T Plates (K080522)
Synthes LCP Distal Tibia Plates (K013248)
Synthes Pilon Plate (K020602)
Depuy Orthopaedics, Inc. Anterolateral and Medial Locking Plating System (K072832)
- Device Description:** The Synthes 2.7mm / 3.5mm LCP Anterolateral Distal Tibia Plates are low-profile plates with a pre-contoured shape designed to conform to the distal tibia. The plates are available in stainless steel and feature specific versions for the right and left tibia.
- Indications for Use:** Synthes 2.7mm / 3.5mm LCP Anterolateral Distal Tibia Plates are indicated for fractures, osteotomies, and non-unions of the distal tibia, especially in osteopenic bone.
- Substantial Equivalence:** Information presented supports the substantial equivalence of the Synthes 2.7mm / 3.5mm LCP Anterolateral Distal Tibia Plates to the predicate devices. The proposed plate has the same indications for use, incorporates the same fundamental product technology and is composed of the same material.
- Preclinical bench testing and analyses were conducted in support of a determination of substantial equivalence including:
- Geometrical bending strength analysis.
 - Static bend testing.
 - Dynamic fatigue testing.
 - Published clinical literature review.



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

Synthes (USA)
% Mr. Karl Nittinger
Regulatory Affairs Manager
1301 Goshen Parkway
West Chester, Pennsylvania 19380

MAY 11 2010

Re: K092812

Trade/Device Name: Synthes (USA) 2.7mm / 3.5mm LCP Anterolateral Distal Tibia Plates
Regulation Number: 21 CFR 888.3030
Regulation Name: Single / multiple component metallic bone fixation appliance and accessories

Regulatory Class: II
Product Code: HRS
Dated: April 15, 2010
Received: April 29, 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.

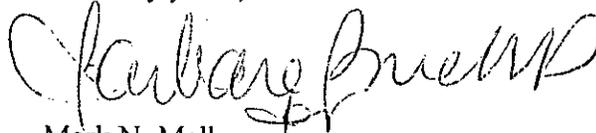
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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



2.0

Indications for Use

510(k) Number (if known): K092812

Device Name: Synthes (USA) 2.7mm / 3.5mm LCP Anterolateral Distal Tibia Plates

Indications for Use:

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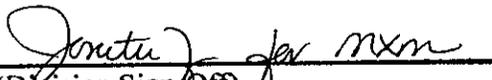
Prescription Use X
(Per 21 CFR 801.109)

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 Surgical, Orthopedic,
and Restorative Devices

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