SYNTHES® K100746

3.0 **510(k) Summary**

Sponsor: Synthes (USA)
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AUG 03 2010

Date Prepared: May 25, 2010

Device Name: Synthes 2.4 mm / 2.7 mm Variable Angle (VA)-LCP Forefoot / Midfoot System

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

Predicate Device:
Synthes 2.4 mm / 2.7 mm Locking Foot Module (K071264)
Synthes Modular Mini Fragment LCP System (K063049)
DARCO Locking Bone Plate System (K061808)
Merete Locking Bone Plate System (K090063)
OrthoHelix Surgical Designs, Inc. MaxLock Extreme™ Extremity Plating System with Variable Angle Technology (K100618)
OrthoHelix Surgical Designs, Inc. Modular Foot System (K073624)
Smith & Nephew VLP Foot Plating System (K090675)

Device Description: The Synthes 2.4/2.7 mm Variable Angle LCP Forefoot / Midfoot System consists of anatomic and procedure specific plates, including 1st MTP Fusion, TMT Fusion, Opening Wedge Osteotomy, X and Straight Fusion, Navicular, Cuboid, and Mesh Plates, with variable angle locking screws and cortex screws to aid in reconstructive foot surgery. The system components are offered in versions composed of implant grade stainless steel and titanium alloy.

Indications: The Synthes 2.4 mm / 2.7 mm VA-LCP Forefoot / Midfoot System is indicated for fixation of osteotomies, fusions, fractures, nonunions, malunions and replantations of small bones and small bone fragments in adult and adolescent (12 – 21 years) patients, including the foot and ankle, and particularly in osteopenic bone.

Substantial Equivalence: Information presented supports substantial equivalence of the Synthes 2.4mm / 2.7mm VA-LCP Forefoot / Midfoot Plates to the predicate devices. The proposed plates have the same indications for use, are similar in design, incorporate the same fundamental product technology and are composed of the same materials. Additionally, calculations comparing the bending strength of the subject and predicate devices based on geometric analyses and the material characteristics defined in standards: ASTM F138-03 and ASTM F1295-05 were performed and the results support substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

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

AUG 03 2010

Re: K100776
Trade/Device Name: Synthes 2.4mm/2.7 mm Variable Angle LCP forefoot/ Midfoot system
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS, HWC
Dated: July 9, 2010
Received: July 13, 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** AUG 03 2010

510(k) Number (if known): K100776

Device Name: Synthes 2.4 mm / 2.7 mm Variable Angle LCP Forefoot / Midfoot System

Indications for Use:

The Synthes 2.4 mm / 2.7 mm Variable Angle LCP Forefoot / Midfoot System is indicated for fixation of osteotomies, fusions, fractures, nonunions, malunions and replantations of small bones and small bone fragments in adult and adolescent (12 -21 years) patients, including the foot and ankle, and particularly in osteopenic bone.

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 K100776

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