K121601

JUL 6 2012

510(k) Summary

Date Prepared: June 22, 2012

Sponsor:	Synthes Angela F. Lassandro 1301 Goshen Parkway West Chester, PA 19380 (610) 719-6854
Device Name:	Synthes 2.7/3.5mm Variable Angle LCP Ankle Trauma System – Anterolateral Distal Tibia Plates
Classification:	Classification: Class II, §888.3030, Single/multiple component metallic bone fixation appliances and accessories. Product Code: HRS, HWC
Predicate Device:	Synthes 2.7/3.5 VA-LCP Ankle Trauma System (K120854) Synthes 4.5/3.5 LCP Metaphyseal Plates (K033805) Zimmer Periarticular and ECT Plate Systems (K040593, K042598, K043227, K043560, K030121, K051098, and Pre-amendment) 3.5mm Cortex Screws (K112583) 3.5 mm Locking Screws (K000684) Synthes 2.7mm VA Locking Screws (K100776) 4.5mm VA Curved Condylar Plate Set (K110354)
Device Description:	The Synthes Anterolateral Distal Tibia Plates are intended to treat fractures of the distal tibia. These plates can be used with a new screw configuration, 3.5mm VA Locking Screws. The Anterolateral Distal Tibia Plates and 3.5mm VA Locking Screws will be offered in both stainless steel and titanium alloy (TAN), and in both sterile and non-sterile configurations. The Anterolateral Distal Tibia Plates will be offered in left and right configurations. The system accepts existing cortical screws, locking screws, dynamic locking screws, and metaphyseal screws (K100776, K063049, K112583, K000684, K111230, K120070, K110592, and K043185) as well as new 3.5mm VA Locking Screws, and allows for both dynamic compression and locking through Combi holes.

Intended Use/ Indications for Use	The Synthes 2.7/3.5mm Variable Angle LCP Ankle Trauma System is intended for fixation of the ankle and is indicated in adults and adolescents (12-21) in which the growth plates have fused, and particularly in osteopenic bone. Specifically, • Anterolateral Distal Tibia Plates are intended for fixation of osteotomies, fractures, nonunions, malunions, and replantations of bones and bone fragments of the diaphyseal and metaphyseal regions of the distal tibia. • Medial and Anteromedial Distal Tibia Plates are intended for fixation of osteotomies, fractures, nonunions, malunions, and replantations of bones and bone fragments of the diaphyseal and metaphyseal regions of the distal tibia, • Distal Tibia T Plates and Distal Tibia L Plates are intended to buttress partial articular fractures and bone fragments of the distal tibia, and • Lateral Distal Fibula Plates are intended for fixation of osteotomies, fractures, nonunions, malunions, and replantations of bones and bone fragments of the diaphyseal and metaphyseal regions of the distal fibula.
Substantial Equivalence:	Both the subject Synthes 2.7/3.5mm VA-LCP Ankle Trauma System and predicate Synthes 2.7/3.5 VA-LCP Ankle Trauma System (K120854), Synthes 4.5/3.5 LCP Metaphyseal Plate (K033805) and Zimmer Periarticular and ECT Plate (K040593, K042598, K043227, K043560, K030121, K051098, and Pre-amendment) Systems have similar indications, design characteristics, materials, and performance characteristics. The subject system has been shown to be at least as strong as the predicate devices through engineering analysis and fatigue strength testing. Similarly, the new screws have been shown to be substantially equivalent to existing screws through analysis and dimensional comparison to the predicate 3.5mm Cortex Screws (K112583) and 3.5mm Locking Screws (K000684).

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

JUL 6 2012

Synthes
% Ms. Angela F. Lassandro
Regulatory Affairs Specialist
1301 Goshen Parkway
West Chester, Pennsylvania 19380

Re: K121601
Trade/Device Name: Synthes 2.7/3.5mm Variable Angle LCP Ankle Trauma System – Anterolateral Distal Tibia Plates
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: May 30, 2012
Received: June 1, 2012

Dear Ms. Lassandro:

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

Indications for Use Statement

510(k) Number (if known): K121601

Device Name: Synthes 2.7/3.5mm Variable Angle LCP Ankle Trauma System

Indications for Use:

The Synthes 2.7/3.5mm Variable Angle LCP Ankle Trauma System is intended for fixation of the ankle in adults and adolescents (12-21) in which the growth plates have fused, and particularly in osteopenic bone. Specifically,

- Anterolateral Distal Tibia Plates are intended for fixation of osteotomies, fractures, nonunions, malunions, and replantations of bones and bone fragments of the diaphyseal and metaphyseal regions of the distal tibia.
- Medial and Anteromedial Distal Tibia Plates are intended for fixation of osteotomies, fractures, nonunions, malunions, and replantations of bones and bone fragments of the diaphyseal and metaphyseal regions of the distal tibia,
- Distal Tibia T Plates and Distal Tibia L Plates are intended to buttress partial articular fractures and bone fragments of the distal tibia, and
- Lateral Distal Fibula Plates are intended for fixation of osteotomies, fractures, nonunions, malunions, and replantations of bones and bone fragments of the diaphyseal and metaphyseal regions of the distal fibula.

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 K121601