K113364 1/1

FEB 29 2012

510(k) Summary

Sponsor:

Synthes (USA)
Rebecca Blank
1301 Goshen Parkway
West Chester, PA 19380
(610) 719-1268

Device Name: 2.7mm LCP Ulna Osteotomy System

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

Class II, §888.3040 – Smooth or threaded metallic bone fixation fastener, HWC

Predicate Device:

K063049- Modular Mini Fragmernt LCP System
K001941- Synthes Modular Foot System (not in comparison table)
K073228 - DC Ulnar Shortening System

Device Description:

The 2.7mm LCP Ulna Osteotomy System consists of two plates, 6-hole and 8-hole which will be available in titanium alloy and stainless steel, to be offered sterile and non-sterile. This system also includes instrumentation which supports transverse and oblique osteotomy cuts as well as plate placement and fixation.

Intended Use:

The 2.7mm LCP Ulna Osteotomy System is indicated for fixation of fractures, osteotomies, nonunions, replantations, and fusions of small bones and small bone fragments, including osteopenic bone in the ulna. The 2.7mm LCP Ulna Osteotomy System is indicated for use in both adults and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by screw fixation.

Substantial Equivalence:

Information presented supports substantial equivalence of the Synthes 2.7mm LCP Ulna Osteotomy System to predicate devices. The proposed system has the same indications for use, is similar in design, incorporates the same fundamental product technology and is composed of the same materials.

To additionally support substantial equivalence, static and dynamic bench testing was performed as well as calculations comparing the bending strength of the subject and predicate devices based on geometric analyses and material characteristics, defined in standard ASTM F382.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Synthes (USA)
% Ms. Rebecca Blank
1301 Goshen Parkway
West Chester, Pennsylvania 19380

FEB 2 9 2012

Re: K113364
Trade/Device Name: 2.7 LCP Ulna Osteotomy 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: February 7, 2012
Received: February 12, 2012

Dear Ms. Blank:

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

510(k) Number (if known): K113364

Device Name: Synthes (USA) 2.7mm LCP Ulna Osteotomy System

Indications for Use:

The 2.7mm LCP Ulna Osteotomy System is indicated for fixation of fractures, osteotomies, nonunions, replantations, and fusions of small bones and small bone fragments, including osteopenic bone in the ulna. The 2.7mm LCP Ulna Osteotomy System is indicated for use in both adults and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by screw fixation.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 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 K113364