K112085 Page 1/2

NOV 17 2011

Attachment B: Updated 510(k) Summary

Date Prepared: November 16, 2011

Sponsor:	Synthes Angela F. Lassandro 1301 Goshen Parkway West Chester, PA 19380 (610) 719-6854
Device Name:	Synthes Pediatric LCP Plates
Classification:	Classification: Class II, §888.3030, Single/multiple component metallic bone fixation appliances and accessories. Product Code: HRS
Predicate Device:	Synthes LCP Pediatric Plate System (K062872, K072095) Synthes Angled Blade Plates (Pre-amendment, K914546) Synthes 3.5mm Curved LCP Plates (K092609)
Device Description:	The system is a collection of plates used to treat fractures and osteotomies of the femur in infants, children, adolescents, and small statured adults. The complete system includes the following: • 3.5mm and 5.0 mm plates with a 90° angle • 2.7mm, 3.5mm and 5.0 mm plates with a 100° angle • 2.7mm, 3.5mm and 5.0 mm plates with a 110° angle • 3.5mm and 5.0 mm plates with a 120° angle • 2.7mm, 3.5mm and 5.0 mm plates with a 130° angle • 3.5mm and 5.0 mm plates with a 140° angle • 3.5mm and 5.0 mm plates with a 150° angle The system accepts existing cortical and locking screws, and features allows for both dynamic compression and locking through Combi holes. The plates are universally designed for both left and right use.
Intended Use:	The Synthes (USA) Pediatric LCP Plate System is indicated for fixation of fractures (including pathologic and impending pathologic fractures) and osteotomies of the femur in infants, children, adolescents and small statured adults. Specific indications for the 100°, 120°, 130°, 140°, 150° plates include: • Varus, valgus, rotational and/or shortening osteotomies • Femoral neck and/or pertrochanteric fractures • Proximal metaphyseal fractures • Diaphyseal fractures • Pathologic fractures • Prophylactic use for impending pathologic fractures

	Specific indications for the 90° plates include: • Varus, valgus, rotational and/or shortening osteotomies • Femoral neck and/or pertrochanteric fractures • Proximal and distal metaphyseal fractures • Diaphyseal fractures • Pathologic fractures • Prophylactic use for impending pathologic fractures •
Substantial Equivalence:	Both the subject Synthes Pediatric LCP Plate System and predicate Synthes LCP Pedaitric Plate System, Angled Blade Plates, and 3.5mm Curved LCP Plates have similar indications, design characteristics, materials, and performance characteristics. Engineering strength analysis and fatigue testing was completed for the plates included in the Synthes Pediatric LCP Plate System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

June 27, 2013

Synthes
% Ms. Angela F. Lassandro
Regulatory Affairs Specialist
1302 Wrights Lane East
West Chester, Pennsylvania 19380

Re: K112085
Trade/Device Name: Synthes LCP Pediatric 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: October 14, 2011
Received: October 18, 2011

Dear Ms. Lassandro:

This letter corrects our substantially equivalent letter of November 17, 2011.

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 contact 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. 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,

For Erin D. Keith

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

Enclosure

Revised Indications for Use Statement

510(k) Number (if known): K112085

Device Name: Synthes Pediatric LCP Plates

Indications for Use:

The Synthes (USA) Pediatric LCP Plate System is indicated for fixation of fractures (including pathologic and impending pathologic fractures) and osteotomies of the femur in infants, children, adolescents and small statured adults.

Specific indications for the 100°, 110°, 120°, 130°, 140°, 150° plates include:

- Varus, valgus, rotational and/or shortening osteotomies
- Femoral neck and/or pertrochanteric fractures
- Proximal metaphyseal fractures
- Diaphyseal fractures
- Pathologic fractures
- Prophylactic use for impending pathologic fractures

Specific indications for the 90° plates include:

- Varus, valgus, rotational and/or shortening osteotomies
- Femoral neck and/or pertrochanteric fractures
- Proximal and distal metaphyseal fractures
- Diaphyseal fractures
- Pathologic fractures
- Prophylactic use for impending pathologic fractures

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)

Elizabeth L. Frank -S

Division of Orthopedic Devices