K072095

SYNTHES®

## 3.0 510(k) Summary



**Sponsor:**
Synthes (USA)
1301 Goshen Parkway
West Chester, PA 19380
(610) 719-5000

SEP 27 2007

**Contact:**
Jill R. Sherman
Synthes (USA)
1301 Goshen Parkway
West Chester, PA 19380
610-719-6538

**Device Name:** Synthes (USA) Pediatric LCP Hip Plate System Modifications

**Classification:** 21 CFR Part 888.3030; Single/multiple component metallic bone fixation appliances and accessories.

**Predicate Device:**
Synthes Pediatric LCP Hip Plate System
Synthes Angled Blade Plates

**Device Description:** The Synthes (USA) Pediatric LCP Hip Plate System is available in 3.5 and 5.0 mm versions which include 100, 110, 120, and 150 degree angles. The plates are designed with three conical locking screw holes located at the head in conjunction with 3 or 4 combination locked-compression screw holes at the shaft. The fixed angle construct is created by means of three standard locking screws inserted through the head of the plate. The shaft of the plate accepts locking or cortex screws, depending on the nature of the fracture or the quality of bone.

The Synthes (USA) Pediatric LCP Hip Plate System Modifications to include 3.5 mm Cortex screws to be utilized with the plates.

The screws are manufactured from 316L stainless steel and available both sterile and non-sterile.

**Intended Use:** The Synthes (USA) Pediatric LCP Hip Plate System is intended for fixation of fractures and osteotomies of the proximal femur in children, adolescents, and small statured adults.
Specific indications include:

- intertrochanteric rotational and/or varus osteotomies
- femoral neck and/or pertrochanteric fractures
- intertrochanteric valgus osteotomies and/or rotational osteotomies

**Substantial Equivalence:** Information presented supports substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 27 2007

Synthes (USA)
% Ms. Jill R. Sherman
Regulatory Affairs / Compliance Specialist
1301 Goshen Parkway
West Chester, Pennsylvania 19380

Re: K072095
Trade/Device Name: Pediatric LCP Hip Plate System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: JDS
Dated: September 14, 2007
Received: September 17, 2007

Dear Ms. Sherman:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SYNTHES®

**2.0** **Revised Indications for Use**

510(k) Number (if known): K072095

Device Name: Synthes (USA) Pediatric LCP Hip Plate System Modifications

Indications for Use: The Synthes (USA) Pediatric LCP Hip Plate System is intended for fixation of fractures and osteotomies of the proximal femur in children, adolescents, and small statured adults.

Specific indications include:

- intertrochanteric rotational and/or varus osteotomies
- femoral neck and/or pertrochanteric fractures
- intertrochanteric valgus osteotomies and/or rotational osteotomies

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)

Mark A Milhern

**(Division Sign-Off)**
**Division of General, Restorative, and Neurological Devices**

**510(k) Number** K072095