

3.0 510(k) SummaryPage 1 of 1**Sponsor:**

Synthes (USA)
1301 Goshen Parkway
West Chester, PA 19380
(610) 719-6940

Contact:

Sheri L. Musgnung
Synthes (USA)
1301 Goshen Parkway
West Chester, PA 19380
(610) 719-6940
FAX (484) 356-9682

NOV 17 2009

Device Name:

Synthes 3.5 mm and 4.5 mm Curved Narrow and Broad Locking Compression Plates (LCP)

Classification:

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

Predicate Device:

Synthes 3.5 mm and 4.5 mm Locking Compression Plate (LCP) System with Expanded Indications (K082807)

Device Description:

The Synthes Curved Narrow and Broad LCP Plates are available in stainless steel and titanium, and consist of limited-contact profile plates in 3.5 mm and 4.5mm narrow and broad sizes. The plates feature Dynamic Compression Plate (DCP) holes combined with locking screw holes. The 3.5mm plates accept 3.5mm cortex and locking screws and 4.0 mm cancellous screws, and the 4.5mm plates accept 4.5 mm cortex screws, 4.0mm and 5.0mm locking screws, 4.5 mm cannulated screws, 5.0 mm periprosthetic screws, and 6.5 mm cancellous screws.

Intended Use:

The Synthes 3.5mm Curved Narrow and Broad LCP Plates are intended for fixation of fractures, osteotomies and non-unions of clavicle, scapula, olecranon, humerus, radius, pelvis, distal tibia and fibula, particularly in osteopenic bone for adult patients.

The Synthes 4.5mm Curved Narrow and Broad LCP Plates are intended for fixation of various long bones, such as the humerus, femur, and tibia. They are also for use in fixation of periprosthetic fractures, osteopenic bone, and non-unions or malunions in adult patients.

The 3.5mm and 4.5mm Curved Narrow and Broad LCP Plates are also indicated for fracture fixation of diaphyseal and metaphyseal areas of long bones in pediatric patients.

**Substantial
Equivalence:**

Information presented supports substantial equivalence.

C00005



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring, MD 20993-0002

Synthes (USA)
% Ms. Sheri L. Musgnung
Regulatory Affairs Manager
1301 Goshen Parkway
West Chester, Pennsylvania 19380

NOV 17 2009

Re: K092609

Trade/Device Name: Synthes 3.5 mm and 4.5 mm Curved Narrow and Broad Locking
Compression Plates (LCP)

Regulation Number: 21 CFR 888.3030

Regulation Name: Single/multiple component metallic bone fixation appliances and
accessories

Regulatory Class: Class II

Product Code: HRS, HWC

Dated: August 24, 2009

Received: August 25, 2009

Dear Ms. Musgnung:

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 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.

Page 2 – Ms. Sheri L. Musgung

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/ucml15809.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" (21 CFR 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

510(k) Number (if known): K092609

Device Name: Synthes 3.5 mm and 4.5 mm Curved Narrow and Broad Locking Compression Plates (LCP)

Indications for Use:

The Synthes 3.5mm Curved Narrow and Broad LCP Plates are intended for fixation of fractures, osteotomies and non-unions of clavicle, scapula, olecranon, humerus, radius, pelvis, distal tibia and fibula, particularly in osteopenic bone for adult patients.

The Synthes 4.5mm Curved Narrow and Broad LCP Plates are intended for fixation of various long bones, such as the humerus, femur, and tibia. They are also for use in fixation of periprosthetic fractures, osteopenic bone, and non-unions or malunions in adult patients.

The 3.5mm and 4.5mm Curved Narrow and Broad LCP Plates are also indicated for fracture fixation of diaphyseal and metaphyseal areas of long bones in pediatric patients.

Prescription Use X
(Per 21 CFR 801.109)

AND/OR

Over-The-Counter Use _____
(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)

[Signature] for Mark Melker
(Division Sign-off)
Division of Surgical Orthopedic,
and Restorative Devices

510(k) Number K092609

000004