DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 13 2009

Synthes (USA)
% Ms. Jill R. Sherman
1301 Goshen Parkway
West Chester, PA 19380

Re: K082807
Trade/Device Name: Synthes (USA) 3.5 mm and 4.5 mm Locking Compression Plate (LCP) System with Expanded Indications
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: September 23, 2008
Received: September 24, 2008

Dear Ms. Sherman:

This letter corrects our substantially equivalent letter of November 24, 2008.

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 (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.

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 continue 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/dsma/dsmamain.html

Sincerely yours,

Mark N. Melkerson

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

Enclosure

2.0 **Indications for Use**

510(k) Number (if known): K082807

Device Name: Synthes (USA) 3.5 mm and 4.5 mm Locking Compression Plate (LCP) System with Expanded Indications

Indications for Use:

Synthes 3.5 mm Locking Compression Plate (LCP) System:

The Synthes 3.5 mm Locking Compression Plate (LCP) System is indicated for fixation of fractures, osteotomies and non-unions of the clavicle, scapula, olectranon, humerus, radius, ulna, pelvis, distal tibia, fibula, particularly in osteopenic bone for adult patients.

These plates are also indicated for fracture fixation of diaphyseal and metaphyseal areas of long bones in pediatric patients.

Synthes 4.5 mm Locking Compression Plate (LCP) System:

The Synthes 4.5 mm Locking Compression Plate (LCP) System is indicated for fixation of various long bones, such as the humerus, femur and tibia and for use in fixation of peri-prosthetic fractures, osteopenic bone and fixation of non-unions or malunions in adult patients.

These plates are also indicated for fracture fixation of diaphyseal and metaphyseal areas of long bones in pediatric patients.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ___X___ AND/OR Over-The-Counter Use_____
(Per 21 CFR 801.109) (21 CFR 807 Subpart C)

Division Sign-Off)
General Restorative,
Neurological Devices

510(k) Number K082807

SYNTHES®

3.0 510(k) Summary

Sponsor:	Synthes (USA) 1301 Goshen Parkway West Chester, PA 19380 (610) 719-5000
Contact:	Jill R. Sherman Synthes (USA) 1301 Goshen Parkway West Chester, PA 19380 Phone: 610-719-6538 Fax: 484-356-9682
Device Name:	Synthes (USA) 3.5 mm and 4.5 mm Locking Compression Plate (LCP) System with Expanded Indications
Classification:	21 CFR Part 888.3030; Single/multiple component metallic bone fixation appliances and accessories.
Predicate Devices:	Smith & Nephew Locking Bone Plate System (K033669) Smith & Nephew Bone Plate System (K993106) Synthes Locking Compression Plates (K000682, K000684, K041911)
Device Description:	Synthes 3.5 mm and 4.5 mm LCP Plates with Expanded Indications consist of 3.5 mm LCP plates, 4.5 mm Narrow LCP Plates, 4.5 mm Broad LCP plates and 4.5 mm Curved Broad LCP Plates for fracture fixation in adults and pediatric patients. These plates accept locking, cortex and cancellous screws.
Intended Use:	Synthes 3.5 mm Locking Compression Plate (LCP) System: The Synthes 3.5 mm LCP is indicated for fixation of fractures, osteotomies and non-unions of the clavicle, scapula, olectranon, humerus, radius, ulna, pelvis, distal tibia, fibula, particularly in osteopenic bone for adult patients. These plates are also indicated for fracture fixation of diaphyseal and metaphyseal areas of long bones in pediatric patients. Synthes 4.5 mm Locking Compression Plate (LCP) System: The Synthes 4.5 mm LCP is indicated for fixation of various long bones, such as the humerus, femur and tibia and for use in fixation of peri-prosthetic fractures, osteopenic bone and fixation of non-unions or malunions in adult patients. These 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.