JAN 1 3 2004

K033556

3.0 510(k) Summary:

Sponsor	Synthes (USA) 1690 Russell Road Paoli, PA 19301 (610) 647-9700
Contact	Bonnie Smith
Device Name	Synthes (USA) LCP® Dynamic Helical Hip System™
Device Classification	21 CFR: 888.3030 – Single/multiple component metallic bone fixation appliance and accessories.
Predicate Device	Synthes Dynamic Helical Hip System
Description of Device	Synthes LCP® Dynamic Helical Hip System is a plate and screw system that consists of a straight plate with an angled barrel that accepts a helical blade. The plates have a grooved undersurface, contain combination locking and dynamic compression holes and are available in various barrel angles and plate lengths. The sideplate combination holes accept 5.0 mm locking screws and 4.5 mm cortex screws.
Indications	Intended to treat stable and unstable intertrochanteric, subtrochanteric and basilar neck fractures in which a stable medial buttress can be reconstructed.
Material	Stainless Steel
Substantial Equivalence	Documentation is provided which demonstrates that the Synthes LCP® Dynamic Helical Hip System is substantially equivalent to other legally marketed Synthes devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 3 2004

Ms. Bonnie J. Smith
Senior Regulatory Affairs Associate
Synthes (USA)
1690 Russell Road
P.O. Box 1766
Paoli, Pennsylvania 19301

Re: K033556
Trade/Device Name: Synthes (USA) LCP® Dynamic Helical Hip System™
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: KTT
Dated: November 7, 2003
Received: November 12, 2003

Dear Ms. Smith:

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 (301) 594-4659. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2. Indications for Use

510(k) Number (if known): K033556

Device Name: Synthes (USA) LCP® Dynamic Helical Hip System™

Indications for Use: To treat stable and unstable intertrochanteric, subtrochanteric and basilar neck fractures in which a stable medial buttress can be reconstructed.

for Mark N Melkerson

K033556

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)