MAR - 1 2004

K033995

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3.0 Summary of Safety and Effectiveness Information [510(k) Summary]

SPONSOR:	Synthes (USA) 1690 Russell Road Paoli, PA 19301 (610) 647-9700 Contact: Lisa M. Boyle
DEVICE NAME:	3.5 mm LCP Distal Humerus System
CLASSIFICATION:	Class II, 21 CFR 888.3030: Single / Multiple component bone fixation appliances and accessories and 888.3040 Smooth/threaded metallic bone fixation fastener
PREDICATE DEVICE:	Synthes 3.5 mm LCP Reconstruction Plate Synthes 2.4 mm Cortex Screw, self-tapping
DEVICE DESCRIPTION:	The Synthes 3.5 mm LCP Distal Humerus System consists of medial and postero-lateral distal humerus plates of various lengths and 2.7 mm locking screws. The plates are pre-contoured to match the anatomy of the distal humerus with a limited contact low profile design. The plate features locking compression holes and conical locking holes which accept 2.4, 3.5, & 4.0 mm cortex screws, 2.4, 2.7 & 3.5 mm locking screws, and 4.0 mm cancellous screws. The System will be available in Stainless Steel and Titanium.
INTENDED USE:	The Synthes 3.5 mm LCP Distal Humerus System is indicated for intraarticular fractures of the distal humerus, comminuted supracondylar fractures, osteotomies, and non-unions of the distal humerus.
SUBSTANTIAL EQUIVALENCE:	Docmentation is provided which demonstrates that the Synthes 3.5 mm LCP Distal Humerus System is substantially equivalent to other legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

3-9-2004

Ms. Lisa M. Boyle
Regulatory Associate
Synthes (USA)
1690 Russell Road
Paoli, Pennsylvania 19301

Re: K033995
Trade/Device Name: Synthes (USA) 3.5 mm LCP Distal Humerus 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: December 22, 2003
Received: December 24, 2003

Dear Ms. Boyle:

This letter corrects our substantially equivalent letter of March 1, 2004 regarding the device named above. The product code was incorrectly listed as KTI. The correct product code is listed above.

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

Enclosure

2.0 Indications for Use Statement

510(k) Number (if known): K033995

Device Name: Synthes (USA) 3.5 mm LCP Distal Humerus System

INDICATIONS/CONTRAINDICATIONS:

The Synthes 3.5 mm LCP Distal Humerus System is indicated for intraarticular fractures of the distal humerus, comminuted supracondylar fractures, osteotomies, and non-unions of the distal humerus.

(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)

Miriam C. Provost

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

510(k) Number K033995