JAN 2 8 2003

K023802

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3.0 Summary of Safety and Effectiveness Information

SPONSOR:	Synthes (USA) 1690 Russell Road Paoli, PA 19301 (610) 647-9700 Contact: Lisa M. Boyle
DEVICE NAME:	Synthes 4.5 mm Titanium LCP Proximal Tibia Plating System
CLASSIFICATION:	Class II, §888.3030 – Plate, Fixation, Bone Class II, §888.3040 - Smooth or threaded metallic bone fixation fastener
PREDICATE DEVICE:	Synthes LCP Proximal Tibia Plating System Synthes Large Fragment LCP T- Plate
DEVICE DESCRIPTION:	The Synthes Titanium 4.5mm LCP Proximal Tibia Plating System consists of 4.5 mm Titanium LCP Proximal Tibia Plates, 5.0 mm Titanium Cannulated Locking and Conical screws, and 4.0 mm and 5.0 mm Titanium Solid Locking screws . The Tibia Plates are contoured to match the anatomy of the proximal tibia with a limited contact low profile design. These are plates designed for either the right or left tibia in a variety of shaft lengths. The plate head has threaded screw holes and 2.0 mm holes for preliminary fixation with k-wires, or meniscal repair with sutures. The plate shaft has combination screw holes (dynamic compression and locking screw holes), that accept 4.5 mm cortex, 6.5 mm cancellous, 5.0 mm cannulated locking, 5.0 mm conical, and 4.0 mm & 5.0 mm locking screws. A titanium screw nut is also utilized with this system.
INTENDED USE:	The Synthes Titanium 4.5 mm LCP Proximal Tibia Plating System is intended for treatment of nonunions, malunions, and fractures of the proximal tibia, including simple, comminuted, lateral wedge, depression medial wedge, bicondylar, combination of lateral wedge and depression, and fractures with associated shaft fracture.
MATERIAL:	Titanium

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 8 2003

Synthes (USA)
Lisa M. Boyle
Regulatory Associate
P. O. Box 1766
1690 Russell Road
Paoli, Pennsylvania 19301

Re: K023802
Trade/Device Name: Synthes 4.5 mm Titanium LCP Proximal Tibia Plating System
Regulation Number: 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS
Dated: November 13, 2002
Received: November 14, 2002

Dear Ms. Boyle:

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.

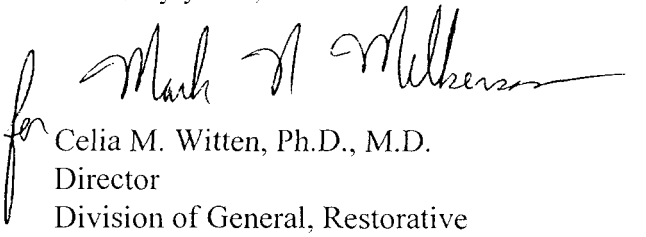
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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). Other general information on your responsibilities under the Act may be obtained 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 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

K023802

2.0 Indications for Use Statement

510(k) Number (if known): _____

Device Name: Synthes (USA) 4.5 mm Titanium LCP Proximal Tibia Plating System

Indications/Contraindications:

The Synthes 4.5 mm Titanium LCP Proximal Tibia System is intended for treatment of nonunions, malunions, and fractures of the proximal tibia, including simple, comminuted, lateral wedge, depression medial wedge, bicondylar combination of lateral wedge and depression, and fractures with associated shaft fractures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

for Mark N Melkerson

(Division Sign-Off)

Division of General Restorative
and Neurological Devices

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