K030597

MAR 2 0 2003

page 1 of 1

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

Sponsor	Synthes (USA) 1690 Russell Road Paoli, PA 19301
Company Contact	Lisa M. Boyle (610) 647-9700 ext. 7593
Name of the Device	Synthes 3.5mm Titanium LCP™ Proximal Tibia Plate
Device Classification	Class II, §888.3030 – Plate, Fixation, Bone, Non-spinal, Metallic
Predicate Device	Synthes 3.5mm SS LCP Proximal™ Tibia Plate Synthes Large Fragment LCP T- Plate
Device Description	The Synthes 3.5mm Titanium LCP™ Proximal Tibia Plates are contoured to match the anatomy of the proximal tibia with a limited contact low profile design. The plates are designed for either the right or left tibia and are available in a variety of lengths. The plates are available in a variety of lengths. The proximal portion of the plate head accepts 3.5mm titanium locking screws, the distal portion of the plate accepts 3.5 mm titanium locking screws, 3.5 mm titanium cortex screws, or 4.0 mm titanium cancellous bone screws.
Indications	Synthes 3.5mm Titanium LCP™ Proximal Tibia Plate is intended treatment of non-unions, malunions, and fractures of the proximal tibia, including simple, comminuted, lateral wedge, depression, medial wedge, bicondylar, combinations of lateral wedge and depression, and fractures with associated shaft fractures.
Materials	Titanium

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 0 2003

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

Re: K030597
Trade/Device Name: Synthes 3.5mm Titanium LCP™ Proximal Tibia Plate
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS
Dated: February 21, 2003
Received: February 25, 2003

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.

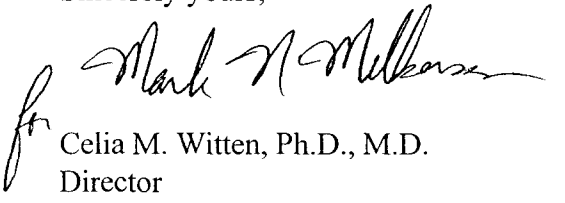
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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



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. Indications for Use Statement

510(k) Number (if known): K030597

Device Name: Synthes 3.5mm Titanium LCP™ Proximal Tibia Plate

Indications for Use:

Synthes Titanium LCP Proximal Tibia Plate is intended treatment of non-unions, malunions, and fractures of the proximal tibia, including simple, comminuted, lateral wedge, depression, medial wedge, bicondylar, combinations 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 Milhern

(Division Sign-Off)
Division of General, Restorative
and [illegible] Devices

510(k) Number K030597