K010766

JUN 1 2 2001

3. 510(k) Summary:

Sponsor	Synthes (USA) 1690 Russell Road Paoli, PA 19301 (610) 647-9700 Contact: Bonnie Smith
Device Name:	Synthes (USA) Large Fragment Locking Compression Plate (LCP) System - T Plate
Device Classification:	21 CFR 888.3030: " Single/multiple component metallic bone fixation appliance and accessories" and 888.3040: "Smooth or threaded metallic bone fixation fastener".
Predicate Device:	Synthes T Plates
Description of Device:	Synthes Locking Compression Plate (LCP) System - T Plate is a buttress plate and screw system. The primary feature of the plate is round holes combined with locking screw holes. The locking screws form a locked, fixed angle construct with the plate, while the standard screws facilitate reduction and create compression between the plate and bone. The plates accept 4.5 mm cortex, 6.5 mm cancellous, 4.5 mm cannulated, 7.0 mm cannulated, 7.3 mm cannulated, 4.0 mm and 5.0 mm locking screws
Indications:	Intended to buttress metaphyseal fractures of the proximal humerus, medial tibial plateau and distal tibia. Also for use in fixation of osteopenic bone and fixation of non-unions and malunions.
Material:	316L Stainless Steel Titanium

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 12 2001

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

Re: K010766
Trade Name: Synthes (USA) Large Fragment Locking Compression Plate (LCP) System - T Plate
Regulation Number: 888.3030
Regulatory Class: Class II
Product Code: KTT
Dated: March 13, 2001
Received: March 14, 2001

Dear Ms. Smith:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/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

Enclosures

2. Indications for Use

510(k) Number (if known): K010766

Device Name: Synthes
Large Fragment Locking Compression Plate (LCP) System - T Plate

Indications for Use: Intended to buttress metaphyseal fractures of the proximal humerus, medial tibial plateau and distal tibia. Also for use in the fixation of osteopenic bone and fixation of non-unions and malunions.

(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)

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

510(k) Number K010766