SYNTHES®

SEP 22 2000

K001945

Attachment VII:

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

SUBMITTER	Synthes (USA) 1690 Russell Road Paoli, PA 19301 (610) 647-9700 Contact: Angela Silvestri
DEVICE NAME:	Synthes Medial Distal Tibia Plates
COMMON OR USUAL NAME	Appliance, Fixation, Nail/Blade/Plate Combination, Single Component; Screw, Fixation, Bone
DEVICE CLASSIFICATION:	Class II, 21 CFR 888.3030 and 888.3040
PREDICATE DEVICE:	Synthes Small T-Plate (pre-76) Synthes One-Third Tubular Plate (pre-76) Synthes 3.5 mm Cortex Screw (pre-76)
DESCRIPTION:	Synthes Medial Distal Tibia Plates are available in two sizes: 3.5 mm and 4.5 mm. They are pre-contoured to fit the distal tibia anatomy. The plates feature a limited contact - dynamic compression plate (LC-DCP) design and are available in right and left versions. The end of the plate includes a hole for a suture, if necessary. The plates accept 3.5 mm, 4.0 mm, 4.5 mm cortex screws, and 4.0 mm cancellous screws.
INTENDED USE:	Synthes Medial Distal Tibia Plates are indicated for the fixation of fractures of the distal tibia including, but not limited to, ankle fractures, periarticular, intraarticular and distal tibia fractures with a shaft extension, malleolar and distal fibular fractures.
MATERIAL:	Stainless Steel and CP Titanium

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 22 2000

Ms. Angela J. Silvestri
Manager, Regulatory Affairs
Synthes (USA)
P.O. Box 1766
1690 Russell Road
Paoli, Pennsylvania 19301

Re: K001945
Trade Name: Synthes (USA) Medial Distal Tibia Plates
Regulatory Class: II
Product Code: HRS
Dated: June 23, 2000
Received: June 26, 2000

Dear Ms. Silvestri:

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 control provisions of the Act. The general control 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

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

Sincerely yours,

Donna R. Lochner

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

SYNTHES®

2.0 Indications for Use Statement

510(k) Number (if known): K001945

Device Name: Synthes (USA) Medial Distal Tibia Plate

Indications For Use:

Synthes Medial Distal Tibia Plates are indicated for the fixation of fractures of the distal tibia including, but not limited to, ankle fractures, periarticular, intraarticular and distal tibia fractures with a shaft extension, malleolar and distal fibular 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)

Anne R. Lochner
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001945