K023941
page 1 of 1

3.0 Summary of Safety and Effectiveness Information

JAN 2 3 2003

SPONSOR:	Synthes (USA) 1690 Russell Road Paoli, PA 19301 (610) 647-9700
COMPANY CONTACT:	Lisa M. Boyle (610) 647-9700
NAME OF DEVICE:	Synthes TomoFix™ Osteotomy System
CLASSIFICATION:	Class II, § 888.3030 – Single / multiple component metallic bone fixation appliance and accessories, and Class II, § 888.3040 - Smooth or threaded metallic bone fixation fastener.
PREDICATE DEVICE:	The Synthes TomoFix™ Osteotomy System is similar to the following Synthes devices which have been cleared via the premarket notification process: Anatomical Locking Plate System, Synthes Locking Condylar Plates , Synthes Large Fragment LCP System, and Synthes LCP Proximal Tibia Plate.
DEVICE DESCRIPTION:	The TomoFix™ Osteotomy System consists of five different titanium plates with locking and combination holes. There are two plates (left and right) for the lateral distal femur, 2 plates (left and right) for the lateral proximal tibia, and 1 plate for the medial proximal tibia.
INTENDED USE:	Synthes TomoFix™ Osteotomy System is intended for open and closed wedge osteotomies of the medial proximal tibia, lateral proximal tibia and lateral distal femur, treatment of bone and joint deformities, and malalignment caused by injury or disease such as osteoarthritis.
MATERIAL:	CP Titanium, Titanium-6Aluminum-7Niobium (Ti-6Al-7Nb)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 23 2003

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

Re: K023941
Trade/Device Name: Synthes TomoFix™ Osteotomy System
Regulation Number: 888.3030; 888.3040
Regulation Name: Single/multiple component metallic bone fixation appliance and accessories; smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: KTT
Dated: November 25, 2002
Received: November 26, 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.

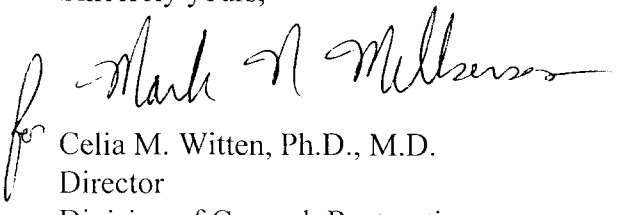
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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



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): _____

Device Name: Synthes (USA) TomoFix™ Osteotomy System

Indications/Contraindications:

Synthes TomoFix™ Osteotomy System is intended for open and closed wedge osteotomies of the medial proximal tibia, lateral proximal tibia and lateral distal femur, treatment of bone and joint deformities, and malalignment caused by injury or disease such as osteoarthritis.

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

510(k) Number K023941