SYNTHES®

APR 1 2 2004

K040762

3. **510(k) Summary:**

Sponsor:	Synthes (USA) 1690 Russell Road Paoli, PA 19301 (610) 647-9700
Contact:	Sheri L. Musgnung
Device Name:	Synthes (USA) Tibial Nail System EX
Device Classification:	21 CFR 888.3020 – "Intramedullary fixation rod" 21 CFR 888.3040 – "Smooth or threaded metallic bone fixation fastener"
Predicate Device:	Synthes Titanium Solid and Cannulated Tibial Nail
Description of Device:	Synthes Tibial Nail System Ex is composed of cannulated tibial nails, 5.0 mm dual core locking screws and end caps. The 5.0 mm dual core locking screws, end caps, and Synthes commercially available locking screws and locking bolts are used to secure the nail in the bone, preventing rotation and axial compression.
Indications:	Synthes Tibial Nail System Ex is intended to stabilize fractures of the proximal and distal tibia and the tibial shaft; open and closed tibial shaft fractures; certain pre- and post-isthmic fractures; and tibial malunions and non-unions.
Material:	Titanium alloy
Substantial Equivalence:	Documentation is provided which demonstrates that the Synthes Cannulated Tibial Nail System EX is substantially equivalent to other legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 2 2004

Ms. Sheri L. Musgnung
Regulatory Affairs Specialist
Synthes (USA)
1690 Russell Road
Paoli, Pennsylvania 19301

Re: K040762
Trade/Device Name: Synthes (USA) Tibial Nail System EX
Regulation Number: 21 CFR 888.3030, 21 CFR 888.3040
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories, Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: JDS,
Dated: March 24, 2004
Received: March 25, 2004

Dear Ms. Musgnung:

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.

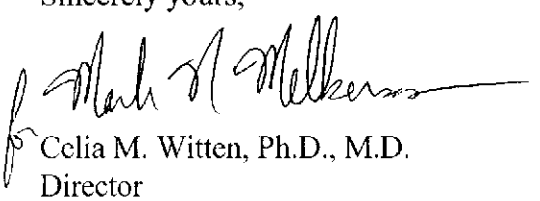
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

SYNTHES®

2. **Indications for Use**

510(k) Number (if known): K040762

Device Name: Synthes (USA) Tibial Nail System EX

Indications for Use: Synthes Tibial Nail System EX is intended to stabilize fractures of the proximal and distal tibia and the tibial shaft; open and closed tibial shaft fractures; certain pre- and post-isthmic fractures; and tibial malunions and non-unions.

Prescription Use X OR Over-The-Counter Use___
(Per 21 CFR 801.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N. Melkerson

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

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510(k) Number K040762