SEP 1 2 2001

K011857

3. Summary of Safety and Effectiveness Information:

Sponsor	Synthes (USA) 1690 Russell Road Paoli, PA 19301 (610) 647-9700 Contact: Bonnie Smith
Device Name:	Synthes (USA) Trochanteric Fixation Nail System
Device Classification:	21 CFR 888.3030: "Single/multiple component metallic bone fixation appliances and accessories" and 888.3040: "Smooth or threaded metallic bone fixation fastener".
Predicate Device:	Howmedica Gamma® Nail System, including modifications for the Long Length and Short Length Gamma® Nails.
Description of Device:	Synthes (USA) Trochanteric Fixation Nail (TFN) System consists of a cannulated intermedullary nail, a cannulated helical blade and cannulated nail end cap. The TFN Nail is anatomically contoured with a proximal diameter of 17 mm, tapering to a nominal diameter of 10, 11 or 12 mm. The proximal locking hole accommodates angles ranging from 125 - 135°. TFN nails are to be available in short lengths (170 - 235 mm) and long lengths (300 - 460 mm), with the long length nails available in right or left versions. The Trochanteric Fixation Nail accepts commercially available Synthes 4.9 mm Locking Bolts and/or 5.0 mm Locking Screws.
Indications:	Synthes Trochanteric Fixation Nail System is intended to treat stable and unstable fractures of the proximal femur including pertrochanteric fractures, intertrochanteric fractures, basal neck fractures, and combinations thereof. The long Trochanteric Fixation Nail is additionally indicated for subtrochanteric fractures, pertrochanteric fractures associated with shaft fractures, pathologic fractures (including prophylactic use) in both trochanteric and diaphyseal regions, long subtrochanteric fractures, proximal or distal non-unions, malunions, and revisions.
Material:	Titanium alloy

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 0 2001

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

Re: K011857
Trade Name: Synthes (USA) Trochanteric Fixation Nail System
Regulation Number: 21 CFR 888.3020 and 888.3040
Regulation Name: Intramedullary fixation rod
Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HSB, HWC
Dated: June 13, 2001
Received: June 14, 2001

Dear Ms. Smith:

This letter corrects our substantially equivalent letter of September 12, 2001, regarding the device name, regulation number and name, and product code.

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.

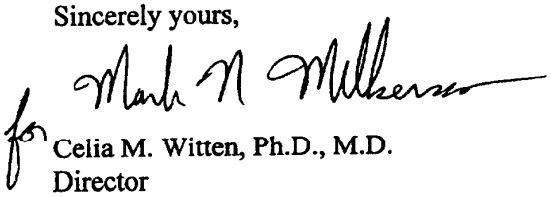
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 and additionally 21 CFR Part 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" (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/dsmamain.html".

Sincerely yours,



for 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**

510(k) Number (if known): K011857

Device Name: Synthes (USA) Trochanteric Fixation Nail System

Indications for Use:

Synthes Trochanteric Fixation Nail (TFN) System is intended to treat stable and unstable fractures of the proximal femur including pertrochanteric fractures, intertrochanteric fractures, basal neck fractures, and combinations thereof. The Long TFN is additionally indicated for subtrochanteric fractures, pertrochanteric fractures associated with shaft fractures, pathologic fractures (including prophylactic use) in both trochanteric and diaphyseal regions, long subtrochanteric fractures, proximal or distal non-unions, malunions, and revisions.

(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 K011857