

FEB - 5 2004

ATTACHMENT III: REVISED 510(k) SUMMARY**Revised 510(k) Summary:**

- Sponsor:** Synthes (USA)
1690 Russell Road
Paoli, PA 19301
(610) 647-9700
- Contact:** Bonnie Smith
- Device Name:** Synthes (USA) Retrograde/Antegrade Femoral Nail System
- Device Classification:** 21 CFR 888.3020 – “Intramedullary fixation rod”
21 CFR 888.3040 – “Smooth or threaded metallic bone fixation fastener”
- Predicate Device:** Synthes Distal Femoral Nail, Synthes Cannulated Femoral Nail, and DePuy ACE ART Femoral Nail.
- Description of Device:** Synthes Retrograde/Antegrade Femoral Nail System is composed of femoral nails, spiral blades and end caps. Depending on the length of the nail, the nail may be inserted from a retrograde approach or from either a retrograde or antegrade approach. Spiral blades, end caps and Synthes commercially available locking bolts and screws are used to secure the nail in the bone, preventing rotation and axial compression.
- Indications:** Synthes Retrograde/Antegrade Femoral Nail System is intended to stabilize fractures of the distal femur and the femoral shaft, including supracondylar fractures, including those with intra-articular extension; ipsilateral hip/shaft fractures; ipsilateral femur/tibia fractures; femoral fractures in multiple trauma patients; fractures proximal to total knee arthroplasty; fractures distal to a hip implant; fractures in the morbidly obese; fractures in osteoporotic bone, impending pathologic fractures; and malunions and nonunions.
- Material:** Titanium alloy
- Substantial Equivalence:** Documentation is provided which demonstrates that the Synthes Retrograde/Antegrade Femoral Nail System is substantially equivalent* to other legally marketed devices.

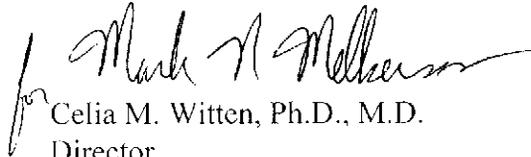
* The term “substantially equivalent” as used in this 510(k) notification is limited to the definition of substantial equivalence found in the Food, Drug, and Cosmetic Act, as amended and as applied under 21 CFR 807, Subpart E, under which a device can be marketed without pre-market approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matter. No statements related to, or in support of substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.

Page 2 - Ms. Bonnie J. Smith

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,

A handwritten signature in black ink, appearing to read "Mark A. Witten". The signature is written in a cursive style and is positioned above the typed name of the signatory.

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

ATTACHMENT II: REVISED INDICATIONS FOR USE

Indications for Use

Page 1 of 1

510(k) Number (if known): K033618

Device Name: Synthes (USA) Retrograde/Antegrade Femoral Nail System

Indications for Use: Synthes Retrograde/Antegrade Femoral Nail System is intended to stabilize fractures of the distal femur and the femoral shaft, including:

- supracondylar fractures, including those with intra-articular extension
- ipsilateral hip/shaft fractures
- ipsilateral femur/tibia fractures
- femoral fractures in multiple trauma patients
- fractures proximal to total knee arthroplasty
- fractures distal to a hip implant
- fractures in the morbidly obese
- fractures in osteoporotic bone
- impending pathologic fractures
- malunions and nonunions

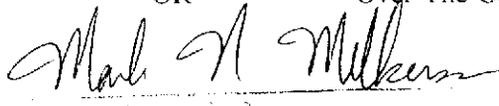
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

OR

Over-The-Counter Use

for 

K033618