SEP 2 1 2005

SYNTHES®

K051678

Revised 510(k) Summary

Sponsor:	Synthes (USA) 1302 Wrights Lane East West Chester, PA 19380 (610) 719-5000
Device Name:	Synthes Hindfoot Arthrodesis Nail System
Classification:	Class II, §888.3020 – Intramedullary Fixation Rod
Predicate Devices:	Biomet Inc. – Titanium Ankle Arthrodesis Nail Synthes – 6.0 mm Locking Screws (accessory in Titanium Distal Femoral Nail System)
Device Description:	Synthes Hindfoot Arthrodesis Nail System is composed of titanium cannulated arthrodesis nails, 6.0 mm Locking Screws, and end caps. Synthes commercially available spiral blades, locking screws, and locking bolts are used to secure the nail in the bone, preventing rotation and axial compression.
Intended Use:	Synthes Hindfoot Arthrodesis Nail System is intended to facilitate tibiotalocalcaneal arthrodesis to treat severe foot/ankle deformity, arthritis, instability, and skeletal defects after tumor resection. These include, but are not limited to Neuro-osteoarthropathy (Charcot's Foot), Avascular Necrosis of the talus, failed joint replacement, failed ankle fusion, distal tibia fracture non-unions, Osteoarthritis, Rheumatoid Arthritis, and Pseudoarthrosis.
Substantial Equivalence:	Documentation was provided which demonstrated the Synthes Hindfoot Arthrodesis Nail System to be 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

SEP 2 1 2005

Ms. Sheri L. Musgnung
Senior Regulatory Specialist
Synthes (USA)
1302 Wrights Lane East
West Chester, Pennsylvania 19380

Re: K051678
Trade/Device Name: Synthes (USA) Hindfoot Arthrodesis Nail System
Regulation Name: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: June 21, 2005
Received: June 23, 2005

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 (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson
Acting 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**

510(k) Number (if known): K051678

Device Name: Synthes (USA) Hindfoot Arthrodesis Nail System

INDICATIONS FOR USE:

The Synthes Hindfoot Arthrodesis Nail System is intended to facilitate tibiotalocalcaneal arthrodesis to treat severe foot/ankle deformity, arthritis, instability, and skeletal defects after tumor resection. These include, but are not limited to Neuro-osteoarthropathy (Charcot's Foot), Avascular Necrosis of the talus, failed joint replacement, failed ankle fusion, distal tibia fracture non-unions, Osteoarthritis, Rheumatoid Arthritis, and Pseudoarthrosis.

Prescription Use ____X____ AND/OR Over-The-Counter Use_____
(Per 21 CFR 801.109) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K051678