SYNTHES®

OCT 7 - 2004

K042135

3.0 510(k) Summary

Sponsor:

Synthes (USA)
1690 Russell Road
Paoli, PA 19301
(610) 647-9700

Device Name: Synthes Elastic Intramedullary Nail (EIN) System (Line Extension)

Classification: 21 CFR 888.3020: Intramedullary fixation rod

Predicate Devices: Synthes Elastic Intramedullary Nail (EIN) System
Depuy Ace Nancy Nail

Device Description: The Synthes EIN system consists of flexible intramedullary fixation devices that vary in diameters and lengths, which can be cut to size intraoperatively. The EIN has a curved tapered tip to facilitate insertion and manipulation. The EIN is manufactured from Titanium Alloy.

Intended Use: The Synthes Elastic Intramedullary Nail (EIN) System is indicated for fixation of diaphyseal fractures where the canal is narrow or flexibility of the implant is paramount. This includes upper extremity fractures in all patients and lower extremity fractures in pediatric or small-stature patients. This system is also intended to treat metaphyseal and epiphyseal fractures, such as radial neck fractures and is intended for fixation of small long bones, such as carpal and tarsal bones. In pediatric applications, the flexibility of the EIN allows it to be inserted at a point which avoids disruption to the bone growth plate.

Substantial Equivalence: Comparative information presented supports substantial equivalence.

The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence found in the Federal Food, Drug and Cosmetic Act, as amended and as applied under 21CFR 807, Subpart E under which a device can be marketed without premarket 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 matters. 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 7 - 2004

Lisa M. Boyle
Regulatory Associate
Synthes (USA)
1690 Russell Road
Paoli, Pensylvania 19301

Re: K042135
Device Name: Synthes (USA) Elastic Intramedullary Nail (EIN) System (Line Extension)
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: II
Product Code: HSB
Dated: August 6, 2004
Received: August 9, 2004

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). 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,

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

SYNTHES®

2.0 **Indications for Use**

510(k) Number (if known): _____

Device Name: Synthes (USA) Elastic Intramedullary Nail (EIN) System (Line Extension)

Indications for Use:

The Synthes Elastic Intramedullary Nail (EIN) System is indicated for fixation of diaphyseal fractures where the canal is narrow or flexibility of the implant is paramount. This includes upper extremity fractures in all patients and lower extremity fractures in pediatric or small-stature patients. This system is also intended to treat metaphyseal and epiphyseal fractures, such as radial neck fractures and is intended for fixation of small long bones, such as carpal and tarsal bones. In pediatric applications, the flexibility of the EIN allows it to be inserted at a point which avoids disruption to the bone growth plate.

for Mark N Milkerson

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

510(k) Number K042135

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)