SYNTHES®

K971783

ATTACHMENT VII: **Summary of Safety and Effectiveness Info. [510(k) Summary]**

JUL 18 1997

SUBMITTER

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

Contact: Angela Silvestri

COMMON OR USUAL NAME: Intramedullary fixation rod/pin

DEVICE CLASSIFICATION: Class II, 21 CFR 888.3020; 888.3040

PREDICATE DEVICE: Landos Nancy Nail (K960642)

DESCRIPTION: Synthes EIN is a flexible intramedullary fixation device. The nail is available in 2.0, 2.5, 3.0, 3.5, and 4.0 mm diameters, each 440 mm in length, which can be cut to size intraoperatively. The EIN has a curved tapered tip to facilitate insertion and manipulation. The EIN is made of a titanium alloy (Ti-6Al-7Nb).

INTENDED USE: The Synthes EIN is intended for fixation of diaphyseal fractures of the long bones where the medullary 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-statured patients. In pediatric applications, the flexibility of the EIN allows it to be inserted at a point which avoids disruption to the bone growth plate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Angela J. Silvestri
Manager, Regulatory Affairs
Synthes (USA)
1690 Russell Road
P.O. Box 1766
Paoli, Pennsylvania 19301

JUL 18 1997

Re: K971783
Synthes (USA) Elastic Intramedullary Nail (EIN) System
Regulatory Class: II
Product Code: HTY
Dated: May 13, 1997
Received: May 14, 1997

Dear Ms. Silvestri:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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 and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SYNTHES®

SYNTHES (USA)
1690 Russell Road
Post Office Box 1766
Paoli, Pennsylvania 19301
Telephone 610-647-9700

510(k) Number (if known): _____

Device Name: Synthes (USA) Elastic Intramedullary Nail System

Indications for use:

The Synthes EIN is intended for fixation of diaphyseal fractures of the long bones where the medullary 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-statured patients. In pediatric applications, the flexibility of the EIN allows it to be inserted at a point which avoids disruption to the bone growth plate.

(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 Devices
510(k) Number K971783

Prescription Use X
(Per 21 CFR 801.109)

OR Over-The-Counter Use