SYNTHES®

SEP 23 1999

K992348

Attachment VI: **Summary of Safety and Effectiveness Information [510(k) Summary]**

SUBMITTER	Synthes (USA) 1690 Russell Road Paoli, PA 19301 (610) 647-9700 Contact: Sheri L. Musgnung
DEVICE NAME:	Synthes Spiral Blade for Humeral Nail (SBHN)
COMMON OR USUAL NAME	Intramedullary fixation rod; Smooth or threaded metallic bone fixation fastener
DEVICE CLASSIFICATION:	Class II, 21 CFR 888.3020 and 888.3040
PREDICATE DEVICE:	Synthes Unreamed Humeral Nail (a.k.a. Solid Humeral Nail)
DESCRIPTION:	Synthes Spiral Blade is used in conjunction with Synthes Solid Humeral Nail. The Synthes SBHN has a self-cutting blade tip, is cannulated, has suture holes located around periphery of blade head, and is available in lengths ranging from 34 mm to 54 mm. A Locking End Cap is used to lock the Spiral Blade in place.
INTENDED USE:	Synthes Spiral Blade for Humeral Nail is intended to stabilize fractures of the humerus.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 23 1999

Ms. Sheri L. Musgnung
Regulatory Affairs Specialist
Synthes (USA)
1690 Russell Road
P. O. Box 1766
Paoli, Pennsylvania 19301

Re: K992348
Trade Name: Synthes Spiral Blade for Humeral Nail
Regulatory Class: II
Product Code: JDS
Dated: July 13, 1999
Received: July 14, 1999

Dear Ms. Musgnung:

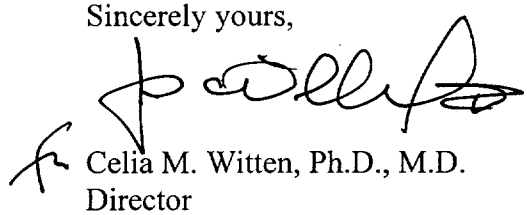
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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) 594-4595. 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,



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®

2.0 Indications for Use Statement

510(k) Number (if known): K992348

Device Name: Synthes Spiral Blade for Humeral Nail

Indications For Use:

Synthes Spiral Blade for Humeral Nail is intended to stabilize fractures of the humerus.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K992348