

SEP - 4 1997

**ATTACHMENT VII: 510(k) Summary of Safety and Effectiveness**

K972516

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

Contact: Angela Silvestri

**COMMON OR USUAL NAME:** Intramedullary fixation rod

**DEVICE CLASSIFICATION** Class II, 21 CFR 888.3020; 888.3040

**PREDICATE DEVICE:** Synthes FlexNail (K953334)

**DESCRIPTION:** Synthes FlexNail is a flexible, non-reamed, locking intramedullary fixation device that is capable of sharing normal weight-bearing loads with the fixed fractured humerus. It locks within the medullary canal at either end of the bone, bridging the fracture and maintaining alignment while the fracture heals. It is available in 7.0, 7.5 and 9 mm diameters, in lengths ranging from 180 to 300 mm (in 15 mm increments). Nail accessories include: a 3.9 mm Ti Locking Bolt for nail interlocking; a Tension Screw that mates with the tension block; and End Cap Screws. The "0 mm" extension End Cap Screw is used to plug the proximal connecting thread of the nail and prevent tissue in-growth to facilitate removal. The "15 mm" extension End Cap Screw protects the proximal thread of the nail and holds the proximal extension segment to the nail. This allows the nail to be overinserted by 15 mm, while leaving the proximal end of the nail accessible for removal. The FlexNail is manufactured from a titanium alloy.

**INTENDED USE:** Synthes FlexNail is intended for treatment of humeral shaft fractures; specifically, it is for treatment of acute humeral shaft fractures, including certain pre- and post-isthmal fractures (including, but not limited to transverse, short oblique, long oblique, butterfly, and segmental fractures, of all grades of comminution); pathologic or impending pathologic fractures; and non- and malunions of the humeral shaft.



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

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Re: K972516  
Synthes (USA) Flexible Humeral Nail (FlexNail) System  
Regulatory Class: II  
Product Code: JDS  
Dated: July 3, 1997  
Received: July 7, 1997

Dear Ms. Silvestri:

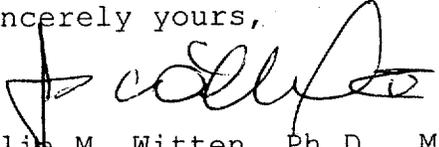
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

  
fn 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



510(k) Number (if known): K972516

Device Name: Synthes (USA) Flexible Humeral Nail (FlexNail) System

Indications for use:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

[Signature]  
(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K972516