



FEB 29 1999

3.0 510(k) Summary

Page 1 of 1

- Sponsor:** Synthes (USA)
Karl J. Nittinger
1301 Goshen Parkway
West Chester, PA 19380
(610) 719-6941
- Device Name:** Synthes Olecranon Osteotomy Nailing System
- Classification:** Class II, 21 CFR 888.3020 – Intramedullary fixation rod.
- Predicate Device:** Pioneer Surgical Technology SS Cables with Crimp
Synthes Kirschner Wires
Synthes 6.5mm Cancellous Screws
Acumed Small Bone Locking Rod System II
Biomet S.S.T. Small Bone Locking Forearm Nail
- Device Description:** Synthes Olecranon Osteotomy Nailing System consists of machined metallic olecranon nails, end caps and screws which are designed for use in fixation of fractures and osteotomies of the olecranon process of the ulna.
- Synthes Olecranon Osteotomy Nailing System offers a unique alternative to current techniques for olecranon fracture and olecranon osteotomy fixation. The system allows for quick realignment of the olecranon fragment following procedures which are primary to the repair of the olecranon osteotomy.
- Intended Use:** Synthes Olecranon Osteotomy Nailing (OleON) System is intended to treat olecranon osteotomies as well as simple fractures of the olecranon.
- Substantial Equivalence:** Information presented supports substantial equivalence.

DP



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 29 2008

Synthes (USA)
% Mr. Karl J. Nittinger
Regulatory Affairs Specialist
1301 Goshen Parkway
West Chester, Pennsylvania 19380

Re: K073402

Trade/Device Name: Olecranon Osteotomy Nailing System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: II
Product Code: HSB
Dated: February 13, 2008
Received: February 15, 2008

Dear Mr. Nittinger:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure



2.0

Indications for Use

510(k) Number (if known): K073402

Device Name: Synthes Olecranon Osteotomy Nailing System

Indications for Use:

Synthes Olecranon Osteotomy Nailing (OleON) System is intended to treat olecranon osteotomies as well as simple fractures of the olecranon.

Prescription Use X
(Per 21 CFR 801.109)

AND/OR

Over-The-Counter Use _____
(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 K073402