

- Sponsor:** Synthes (USA)
Karl J. Nittinger
1301 Goshen Parkway
West Chester, PA 19380
(610) 719-6941
FAX (484) 356-9682
- MAR - 2 2011
- Date Prepared:** October 4, 2010
- Device Name:** Synthes MultiLoc Proximal Humeral Nailing System
- Classification:** Class II, §888.3020 – Intramedullary fixation rod
Product Code: HSB
- Predicate Device:**
- Synthes Cannulated Titanium Humeral Nail System (K033071)
 - Tornier Aequalis Humeral Nail System (K082754)
 - Synthes Angular Stable Locking System [ASLS] (K090241)
 - Synthes 4.0mm and 5.0mm Locking Screws (K000089)
 - Synthes 3.5mm LCP Proximal Humerus Plates (K041860)
 - Synthes 3.5mm Locking Screws (K000684)
- Device Description:** The Synthes MultiLoc Proximal Humeral Nailing System consists of metallic rods and accessories which are intended for implantation in the medullary canal of the proximal humerus for the fixation of fractures.
- The system features intramedullary nail devices, as well as 4.5mm bone screw and end cap accessories. The nails are cannulated, are offered in 8.0mm and 9.0mm diameters, and 160mm in overall length. The nail, screw, and end cap devices are composed of titanium alloy. The nails additionally feature a polymer inlay in the proximal end to enhance the stability of the 4.5mm MultiLoc proximal locking screws. The 4.5mm MultiLoc Screws which are used to facilitate the proximal locking of the nail construct can be interlocked with existing Synthes 3.5mm Locking Screws to enhance the stability of the construct.
- Indications for use:** The Synthes MultiLoc Proximal Humeral Nailing System is indicated for fractures of the proximal humerus, including 2-part surgical neck fractures, 3-part fractures, and 4-part fractures.
- Substantial Equivalence:** Information presented supports substantial equivalence of the Synthes MultiLoc Proximal Humeral Nailing System to the predicate devices. The proposed system has the same indications for use, is similar in design, incorporates the same fundamental product technology and is composed of the same materials.

K103002 #2/a

**Substantial
Equivalence
(continued):**

To additionally support substantial equivalence, calculations comparing the bending strength of the subject and predicate devices based on geometric analyses and material characteristics defined in standard ASTM F1295-05 were performed as well as *in vitro* mechanical testing. The *in vitro* bench testing included static and dynamic bend, torsional strength, and dynamic fatigue strength of the construct and was conducted in comparison with the predicate devices and the results support substantial equivalence.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

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

MAR - 2 2011

Re: K103002

Trade/Device Name: Synthes Multiloc Proximal Humeral Nailing System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: February 07, 2011
Received: February 09, 2011

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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

Page 2 – Mr. Karl J. Nittinger

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



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

Enclosure



2.0

Indications for Use

510(k) Number (if known): K103002

Device Name: Synthes MultiLoc Proximal Humeral Nailing System

Indications for Use:

Synthes MultiLoc Proximal Humeral Nailing System is indicated for fractures of the proximal humerus, including 2-part surgical neck fractures, 3-part fractures, and 4-part fractures.

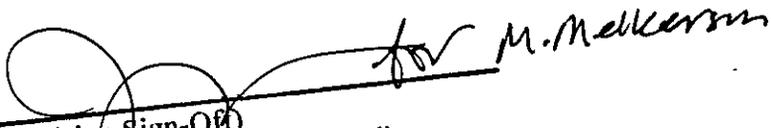
Prescription Use X
(Per 21 CFR 801.109)

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 Surgical, Orthopedic,
and Restorative Devices

510(k) Number K103002