K092190 (pg 1/1)

3.0 510(k) Summary

MAY 11 2010

Sponsor: Synthes (USA)
1301 Goshen Parkway
West Chester, PA 19380 Phone: (610) 719-5000

Contact: Jill R. Yelton, Regulatory Compliance Manager

Device Name: Synthes Distraction Osteogenesis System, MR Conditional with Expanded Indications

Classification: 21 CFR Part 888.3030; Single/multiple component metallic bone fixation appliances and accessories.

Predicate Devices: Synthes Distraction Osteogenesis System
Synthes Large External Fixation, MR Conditional

Device Description: The Synthes Distraction Osteogenesis System, MR Conditional with Expanded Indications is an external ring fixation system. The system is comprised of wires and Schanz screws that are attached to rings with bolts, nuts and/or clamps; rods that interconnect the rings; and connecting plates, hinges, standoffs, posts, supports and distractors that complete the assembly of the fixator. This system is a versatile system that is fully customizable. An individualized frame should be constructed for each case to suit the specific situation. The materials of construction for this system include implant grade titanium, elgiloy, stainless steel and carbon fiber.

Intended Use: The Synthes Distraction Osteogenesis System, MR Conditional is intended for fracture fixation (open and closed), pseudoarthrosis or non-unions of long bones, limb lengthening by epiphyseal or metaphyseal distraction, correction of bony or soft tissue deformities and correction of segmental bony or soft tissue defects in adult and pediatric patients.

Substantial Equivalence Information presented supports the substantial equivalence of the Synthes Distraction Osteogenesis System, MR Conditional with Expanded Indications to the predicate devices. The proposed devices have the same indications for use with addition of MR Conditional and Pediatric, are similar in design, incorporate the same fundamental product technology and are composed of the same materials. MR testing was performed in accordance with current ASTM Standards, F-2503, F-2052, F-2213 and F-2182 for marking and standard test methods for displacement force, torque and RF heating, IEC 60601-2-33 for safety in a Magnetic Resonance Environment and Guidance for Industry and FDA Staff, "Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment". Engineering performance evaluation and analysis was performed comparing the proposed devices to the predicate devices and an Engineering analysis was performed and documentation provided to support addition of pediatric indications. The results support substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Synthes (USA)
% Jill Yelton
1301 Goshen Parkway
West Chester, Pennsylvania 19380

MAY 11 2010

Re: K092190
Trade/Device Name: Synthes Distraction Osteogenesis System, MR Conditional with Expanded Indications
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: KTT
Dated: April 16, 2010
Received: April 19, 2010

Dear Ms. Yelton:

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 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); 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" (21CFR 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 (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Barbara Buehrle for

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): K092190 (pg 1/1)

Device Name: **Synthes Distraction Osteogenesis System, MR Conditional with Expanded Indications**

Indications for Use:

The Synthes Distraction Osteogenesis System, MR Conditional is intended for fracture fixation (open and closed), pseudoarthrosis or non-unions of long bones, limb lengthening by epiphyseal or metaphyseal distraction, correction of bony or soft tissue deformities and correction of segmental bony or soft tissue defects in adult and pediatric patients.

Prescription Use __X__ AND/OR Over-The-Counter Use_____
(Per 21 CFR 801.109) (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 K092190