

3.0 510(k) SummaryPage 1 of 2

- Sponsor:** Synthes (USA)
1302 Wrights Lane East
West Chester, PA 19380
(610) 719-5860
- Device Name:** Synthes (USA) Distraction Osteogenesis System
- Classification:** Class II, §888.3030 – Single/multiple component bone fixation appliances and accessories
- Predicate Devices:** Smith & Nephew Ilizarov External Fixation System
Encore True/Lok External Fixation System
- Device Description:** The Synthes Distraction Osteogenesis System 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 and supports that complete the assembly of the fixator. The system components are made from nonmagnetic materials and are intended to be used in an MR environment. An MR environment is described as the general environment present in the vicinity of an MR scanner and/or anywhere in the procedure room, including the center of the bore of the MR scanner.
- The Synthes Distraction Osteogenesis System is a modular and versatile system that is fully customizable. An individualized frame should be constructed for each case to suit the specific situation.
- Intended Use:** The Synthes Distraction Osteogenesis System is intended for fracture fixation (open and closed), pseudoarthrosis or nonunions 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.
- Substantial Equivalence:** Documentation is provided which demonstrates that the Synthes (USA) Distraction Osteogenesis System is substantially equivalent to other legally marketed devices.

The term “substantial equivalence” as used in this 510(k) notification is limited to the definition of substantial equivalence found in the Federal Food, Drug and Cosmetic Act, as amended and as applied under 21CFR 807, Subpart E under which a device can be marketed without premarket approval or reclassification. A

determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.



JUL 27 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Kathy Anderson
Regulatory Affairs Manager
Synthes (USA)
1302 Wrights Lane East
West Chester, Pennsylvania 19380

Re: K051600
Trade/Device Name: Synthes (USA) Distraction Osteogenesis System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation
appliances and accessories
Regulatory Class: II
Product Code: KTT
Dated: July 21, 2005
Received: July 22, 2005

Dear Ms. Anderson:

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.

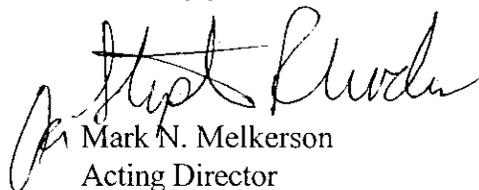
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

Page 2 - Ms. Kathy Anderson

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 Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson". The signature is written in a cursive style with a large initial "M".

Mark N. Melkerson
Acting 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): _____

Device Name: Synthes (USA) Distraction Osteogenesis System

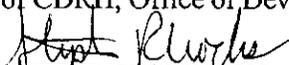
Indications for Use:

The Synthes Distraction Osteogenesis System is intended for fracture fixation (open and closed), pseudoarthrosis or nonunions 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.

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 General, Restorative
and Neurological Devices

510(k) Number K051600