JAN 1 8 2005

K043039

3.0 510(k) Summary

Sponsor:

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

Device Name: Synthes (USA) External Fixation Component Line Extension – MR Safe

Classification: Class II, §888.3030 – Single/multiple component bone fixation appliances and accessories

Predicate Device:
Synthes Reprocessed External Fixation Devices
Hoffmann II External Fixation System (Stryker)
EBI XFIX Vision Fixation System

Device Description: Synthes External Fixation Systems, MR Safe are a system of components that form a construct intended to treat stable and unstable fractures. All frame elements are made from non-magnetic materials and are intended for use in the MR environment. This line extension consists of Synthes Pin Clamps with Outrigger Posts and additional Curved Carbon Fiber Rods. These components are also intended for use in the MR environment.

Intended Use: Synthes External Fixation Devices – **MR Safe** are intended for use in the construction of an external fixation frame for treatment of various fracture types that require external fixation

Substantial Equivalence: Documentation is provided which demonstrates that the Synthes (USA) External Fixation Component Line Extension – MR Safe 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 18 2005

Ms. Kathy Anderson
Synthes (USA)
1690 Russell Road
Paoli, Pennsylvania 19301

Re: K043039
Trade/Device Name: Synthes (USA) External Fixation Component Line Extension – MR Safe
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: KTT
Dated: November 2, 2004
Received: November 4, 2004

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.

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/industry/support/index.html.

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SYNTHES®

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

2.0 **Indications for Use**

510(k) Number K043039

510(k) Number (if known): _____

Device Name: **Synthes (USA) External Fixation Component Line Extension – MR Safe**

Indications for Use:

Synthes External Fixation Devices – **MR Safe** are intended for use in the construction of an external fixation frame for treatment of various fracture types that require external fixation.

LARGE
Provide treatment for long bone and pelvic fractures that require external fixation. Specifically, the components can be used for:

- Stabilization of soft tissues and fractures
- Poyltrauma/multiple orthopedic trauma
- Vertically stable pelvic fractures, or as a treatment adjunct for vertically unstable pelvic fractures
- Arthrodeses and osteotomies with soft tissue problems; failures of total joints
- Neutralization of fractures stabilized with limited internal fixation
- Non-unions/septic non-unions
- Intra-operative reductions/stabilization tool to assist with indirect reduction
- Unilateral rectilinear bone segment transport or leg lengthening

MEDIUM
Indicated for construction of an external fixation frame for the treatment of pediatric and adult fractures.

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)