SYNTHES®

NOV - 5 2003

3.0 510(k) Summary

k033158

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

Device Name: Synthes Reprocessed External Fixation Devices

Classification: Class II, 21 CFR §888.3030 – Single/multiple component bone fixation appliances and accessories.

Predicate Devices: Synthes External Fixation Devices

Device Description: Synthes Reprocessed External Fixation Devices consist of various clamps, rods, tubes, bars and rings that are used to construct an external fixation frame. These devices are for single use only, and have been returned to Synthes for reprocessing.

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

Substantial Equivalence: Mechanical testing demonstrates that Synthes Reprocessed External Fixation Devices were shown to be equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 5 2003

Ms. Angela J. Silvestri
Manager, Regulatory Affairs
Synthes (USA)
1690 Russell Road
P.O. Box 1766
Paoli, PA 19301

Re: K033158
Trade/Device Name: Synthes (USA) Reprocessed External Fixation Devices
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: KTT
Dated: September 29, 2003
Received: September 30, 2003

Dear Ms. Silvestri:

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 (301) 594-4659. 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,

for 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

2.0 Indications for Use Statement

510(k) Number (if known): _____

Device Name: Synthes (USA) Reprocessed External Fixation Devices

INDICATIONS: Synthes External Fixation Devices are intended for use in the construction of an external fixation frame for treatment of various fracture types that require external fixation.

LARGE/HYBRID
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
- Hybrid components are designed for fixation of complex proximal and distal tibia fractures, particularly those involving the joint, when soft tissue injuries preclude open reduction and internal fixation, or the fracture pattern does not allow placement of Schanz screws for construction of a standard external fixation frame

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

(Indications are continued on the next page)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

Mark N Millerson
(Division Sign-Off)
Division of General, Restorative and Neurological Devices
510(k) Number K033158

SYNTHES®

2.0 Indications for Use Statement (continued)

510(k) Number (if known): _____

Device Name: Synthes (USA) Reprocessed External Fixation Devices

(Indications continued from previous page)

SMALL
Stabilizes and provides treatment for fractures of the small bones, such as the hand, wrist, forearm, foot, and ankle. Specifically, the components can be used for:

- Preliminary fixation before ORIF
- Unstable fractures of the distal radius (both intra- and extra-articular)
- Open and/or comminuted bilateral fractures
- Fractures in combination with extensive soft tissue injury, bone loss, and vascular and/or neural involvement
- Fracture dislocations
- Failed closed reduction with casting resulting in secondary deformity (radial shortening and angulations)
- Pediatric open fractures with bone loss and osteotomies

MINI
Stabilizes and provides treatment for fractures of the hand and foot. Specifically, the components can be used for:

- Comminuted fractures of phalanges and metacarpals
- Displaced intra-articular fractures
- Segmental bone loss
- Open fractures that do not allow stable internal fixation
- Fractures with associated complex soft tissue injuries
- Tumor resections

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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(Division Sign-Off)
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Concurrence of CDRH, Office of Device Evaluation (ODE)

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