SYNTHES®

MAR 2 3 2004

K040258

3.0 510(k) Summary

Sponsor:

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

Device Name:

Synthes Medium External Fixation System – MR Safe

Classification:

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

Predicate Devices:

Synthes Medium External Fixation System

Device Description:

Synthes Medium External Fixation System – MR Safe is a system of components that form a construct intended to treat stable and unstable fractures. Frame components designed for this system are the Medium Multi-Pin Clamps (four / six position) – MR Safe, the Medium Combination Clamp – MR Safe, the 8.0 mm/11.0 mm Combination Clamp – MR Safe and the Medium Open Adjustable Clamp – MR Safe. Also included in this MR Safe system are the Medium Dynamization Clip and Medium Rod Attachment, which are accessories to the Combination and Multi-Pin Clamps, respectively. These clamp accessories allow dynamization during bone healing and double stacking of the frame. The system accepts Synthes 8.0 mm carbon fiber rods (in lengths from 100 - 500 mm) and Schanz screws (in diameters of 4.0 - 5.0 mm).

All frame elements are made from non-magnetic materials and are intended for use in the MR environment.

Intended Use:

Intended for use in the construction of an external fixator frame for the treatment of pediatric and adult fractures.

Material:

Stainless steel, titanium alloy and cobalt alloy

Substantial Equivalence:

Documentation is provided in this premarket notification that demonstrates that Synthes Medium External Fixation System – MR Safe is substantially equivalent to other legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 3 2004

Ms. Angela J. Silvestri
Manager, Regulatory Affairs
Synthes (USA)
1690 Russell Road
Paoli, Pennsylvania 19301

Re: K040258
Trade/Device Name: Synthes (USA) Medium External Fixation System – 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: February 3, 2004
Received: February 4, 2004

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 Mark N. Melkerson

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®

2.0 Indications for Use Statement

510(k) Number (if known): K040258

Device Name: Synthes (USA) Medium External Fixation System – MR Safe

Indications: The Synthes (USA) Medium External Fixation System is intended for use in the construction of an external fixator frame for the treatment of pediatric and adult fractures.

for Mark N Milhous

(Division Sign-Off)
Division of General, [illegible]
and Neurological D[illegible]

510(k) Number K040258

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use

(Per 21 CFR 801.109)