K011034

JUN 2 7 2001

3.0 510(k) Summary

Sponsor:

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

Contact: Bonnie Smith

Device Name: Synthes Medium External Fixation System

Classification: The classification of the Synthes Medium External Fixation System is Class II, as per Title 21 of the Code of Federal Regulations, Sections 888.3030: "Single/multiple component bone fixation appliances and accessories" and 888.3040: "Smooth or threaded metallic bone fixation fastener". The instruments used with this system are considered Class I Exempt, as per 21 CFR 888.4540: "Orthopedic manual surgical instruments".

Predicate Device: The predicate device for the Synthes Medium External Fixation System is the Howmedica Hoffmann® II External Fixation System. Synthes Medium Dynamization Clip, a component accessory to the system, is similar to the currently marketed Synthes Dynamization Clip.

Device Description: Synthes Medium External Fixation System 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 Clamp and the Medium Combination Clamp. Also included in the system are the Medium Dynamization Clip and Medium Rod Attachment, which are accessories to the clamps that allow dynamization during bone healing and double stacking of the frame, respectively. The system is used with Synthes 8.0 mm carbon fiber rods ranging in lengths from 100 – 500 mm. System pin clamps accept Schanz screws in diameters of 4.0, 4.5 and 5.0 mm.

Intended Use: 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.

Materials:

Clamps –Stainless steel and titanium alloy
Dynamization Clip – Stainless steel
Rod Attachment – Stainless steel and titanium alloy
Rods – Carbon fiber reinforced epoxy (CFRE)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 7 2001

Ms. Bonnie J. Smith
Senior Regulatory Affairs Associate
Synthes (USA)
1690 Russell Road
P.O. Box 1766
Paoli, Pennsylvania 19301

Re: K011034
Trade Name: Synthes (USA) Medium External Fixation System
Regulation Number: 888.3030
Regulatory Class: Class II
Product Code: KTT
Dated: April 4 , 2001
Received: April 5, 2001

Dear Ms. Smith:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.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

Enclosures

2.0 Indications for Use Statement

510(k) Number (if known): K011034

Device Name: Synthes (USA) Medium External Fixation System

INDICATIONS: Synthes Medium External Fixation System is intended for the construction of an external fixator frame for the treatment of pediatric and adult fractures.

(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)

D. Mitchell MA for CAW
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K011034