K010344

MAY - 3 2001

3.0 510(k) Summary

Sponsor:

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

Contact: Bonnie Smith

Device Name: Synthes Adjustable Large Fixator System

Classification: The classification of the Synthes Adjustable Large Fixator 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 Adjustable Large Fixator System is the Synthes Large External Fixator, (a pre-amendment device). The Adjustable Large Fixator System is similar in design and function to other large fixators that have received 510(k) clearance, including the EBI DynaFix™ System.

Device Description: The Adjustable Large Fixator System consists of a pre-assembled, mechanically adjustable, unilateral fixator and an accessory, the Hybrid Adaptor. The fixator is a one-piece construct comprised of radiolucent plastic and metallic components. The vise clamps of the fixator accept 4.0–6.0 mm Schanz Screws. The Hybrid Adaptor is an accessory to the Adjustable Large Fixator that forms the connection between the fixator and the Synthes Hybrid Ring.

Intended Use: The Synthes (USA) Adjustable Large Fixator System is intended for use in the treatment of conditions of the long bones including fractures, osteotomies, and other bone conditions amenable to treatment with a unilateral external fixator.

Material: The Adjustable Large Fixator is comprised of PEEK resin (radiolucent material), aluminum, stainless steel and titanium alloy. The Hybrid Adaptor is comprised of titanium alloy and stainless steel.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 3 2001

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

Re: K010344
Trade Name: Adjustable Large Fixator System
Regulation Number: 888.4540
Regulatory Class: Class II
Product Code: KTT
Dated: February 2, 2001
Received: February 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): K010344

Device Name: Synthes (USA) Adjustable Large Fixator System

INDICATIONS: The Synthes (USA) Adjustable Large Fixator System is intended for use in the treatment of conditions of the long bones including fractures, osteotomies, and other bone conditions amenable to treatment with a unilateral external fixator.

NRO for cmw
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010344

(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)