SEP - 5 2003

K031973

3.0 510(k) Summary

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

Contact: Bonnie Smith

Device Name: Synthes 4.0 mm Adjustable Clamp for Distal Radius Fixator – MR Safe

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

Predicate Device: Synthes 4.0 mm Adjustable Clamp for Distal Radius Fixator

Device Description: Synthes Distal Radius Fixator consists of frame elements that form a construct intended to treat fractures of the distal radius. The Distal Radius Fixator provides stabilization of fractures via pins (Schanz screws) inserted proximally and distally to a fracture and connected by an external bridging frame consisting of two 4.0 mm Adjustable Clamps, a carbon fiber rod and two protective end caps. This device is intended for use in the MR environment. The Distal Radius Fixator is available as a complete sterile assembly or as individual, nonsterile components.

Intended Use: Intended for the stabilization of fractures of the distal radius.

Materials: Clamps – Stainless steel, titanium alloy and cobalt alloy

Substantial Equivalence: Documentation is provided which demonstrates that the Synthes 4.0 mm Adjustable Clamp for Distal Radius Fixator -MR Safe is substantially equivalent to other legally marketed Synthes devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 5 2003

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

Re: K031973
Trade/Device Name: Synthes 4.0 mm Adjustable Clamp for Distal Radius Fixator – MR Safe
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: LXT
Dated: June 25, 2003
Received: June 26, 2003

Dear Ms. Smith:

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): K031973

DEVICE NAME: Synthes 4.0 mm Adjustable Clamp for Distal Radius Fixator – MR Safe

INDICATIONS: Synthes 4.0 Adjustable Clamp for Distal Radius Fixator -MR Safe is part of a construct intended for the stabilization of fractures of the distal radius.

for Mark N Milhous

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

510(k) Number K031973

(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)