K033411

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3. Summary of Safety and Effectiveness Information [510(k) Summary]

Submitter:	Synthes (USA) 1690 Russell Road Paoli, PA 19301
Company Contact:	Bonnie Smith (610) 647-9700
Name of the Device:	Synthes (USA) Sterile Adjustable Distal Radius Fixator (ADRF) with 4.0 mm/3.0 mm Self-Drilling Schanz Screws
Classification:	Class II, 21 CFR 888.3030 and 888.3040
Common or Usual Name:	External Fixation Frame
Predicate (unmodified) Device:	Synthes (USA) Articulating ("Adjustable") Distal Radius Fixator (ADRF)
Device Description:	The Sterile Adjustable Distal Radius Fixator is a pre-assembled mechanically adjustable external wrist fixator. It is a one-piece construct, which consists of plastic and metal components. The device is applied to the bone with four self-drilling Schanz screws that lock into two fixator clamps. The device operates by turning screws, which operate gears, to achieve incremental movement. The sterile packaged ADRF is packaged with Synthes 4.0 mm/3.0 mm stainless steel, self-drilling Schanz screws or Synthes 4.0 mm/3.0 mm titanium self-drilling Schanz Screws.
Intended Use:	Synthes Sterile Adjustable Distal Radius Fixator (ADRF) is intended for fixation of the distal radius.
Material:	Polyetherimide, stainless steel, and titanium alloy
Substantial Equivalency:	Documentation is provided which demonstrates that the Synthes Sterile Adjustable Distal Radius Fixator is substantially equivalent to its predicate device.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 26 2003

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

Re: K033411
Trade/Device Name: Synthes Sterile Adjustable Distal Radius Fixator (ADRF)
Regulation Numbers: 21 CFR 888.3030 and 888.3040
Regulation Names: Single/multiple component metallic bone fixation appliances and accessories, and Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Codes: KTT and HWC
Dated: October 24, 2003
Received: October 27, 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 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

2. Indications for Use

Special 510(k) Device Modification

INTENDED USE STATEMENT

510(k) Number (if known): K033411

Device Name: Synthes Sterile Adjustable Distal Radius Fixator (ADRF)

Indications: Synthes Sterile Adjustable Distal Radius Fixator System is intended for stabilizing fractures of the distal radius.

for Mark N Milham

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

510(k) Number K033411

(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)