APR 1 1 2005

K050631

3.0 510(k) Summary

Sponsor:

Synthes (USA)
1302 Wrights Lane East
West Chester, PA 19380
(610) 719-5000

Device Name: Synthes (USA) Small Adjustable Clamp – MR Safe Line Extension

Classification: Class II, §888.3030 – Single/multiple component bone fixation appliances and accessories

Predicate Device: Synthes 4.0 mm Adjustable Clamp for Distal Radius Fixator – MR Safe
Synthes Small Combination Clamp – MR Safe

Device Description: Synthes Small Adjustable Clamps – MR Safe Line Extension are components of an external fixation frame that forms a construct intended to treat the hand, wrist, mandible and foot. They are all made from non-magnetic materials and are intended to be used in an MR environment. An MR environment is described as the general environment present in the vicinity of an MR Scanner and/or anywhere in the procedure room, including the center of the bore of the MR Scanner. When used in a frame construct, the Small Adjustable Clamp-MR Safe accepts Synthes 4.0 mm carbon fiber rods and Synthes 4.0/4.0, 4.0/3.0 and 4.0/2.5 mm Schanz screws.

Intended Use: Synthes Small Adjustable Clamps – MR Safe Line Extension are intended for fractures of the distal radius, fractures and dislocations of the hand, wrist, mandible and foot (including open and/or bilateral fractures); fractures in combination with extensive soft tissue injury, bone loss, vascular and/or neural involvement; and failed closed reduction and casting resulting in secondary deformity of the distal radius.

Substantial Equivalence: Documentation is provided which demonstrates that the Synthes (USA) Small Adjustable Clamps– MR Safe Line Extension 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

APR 1 1 2005

Ms. Sheri L. Musgnung
Sr. Regulatory Affairs Specialist
Synthes (USA)
1302 Wrights Lane East
West Chester, Pennsylvania

Re: K050631
Trade/Device Name: Synthes (USA) Small Adjustable Clamp – MR Safe Line Extension
Regulation Numbers: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Codes: LXT
Dated: March 10, 2005
Received: March 11, 2005

Dear Ms.Musgnung:

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.

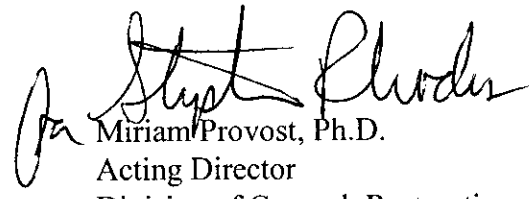
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-0120. 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/industry/support/index.html.

Sincerely yours,



Miriam Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SYNTHES®

Indications for Use

510(k) Number (if known): _____

Device Name: **Synthes (USA) Small Adjustable Clamp – MR Safe Line Extension**

Indications for Use:

Synthes Small Adjustable Clamps – MR Safe Line Extension are intended for fractures of the distal radius, fractures and dislocations of the hand, wrist, mandible and foot (including open and/or bilateral fractures); fractures in combination with extensive soft tissue injury, bone loss, vascular and/or neural involvement; and failed closed reduction and casting resulting in secondary deformity of the distal radius.

Prescription Use X AND/OR Over-The-Counter Use_____
(Per 21 CFR 801.109) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K050631