SYNTHES®

3.0 510(k) Summary

Sponsor:
Synthes (USA)
1301 Goshen Parkway
West Chester, PA 19380
(610) 719-5000

Contact:
Angela Silvestri
Synthes (USA)
1301 Goshen Parkway
West Chester, PA 19380
(484) 356-9728

AUG 24 2007

Device Name: Synthes (USA) 2nd Generation Pelvic C-Clamp

Classification: The classification of the Synthes Pelvic C-Clamp 2nd Generation, as per 21 of the Code of Federal Regulations, Section 888.3040 – Smooth of threaded metallic bone fixation fastener.

Predicate Device: Synthes (USA) Pelvic C-Clamp

Device Description: The Synthes 2nd Generation Pelvic C-Clamp is an emergency stabilization instrument for unstable injuries and fractures of the pelvic ring. It is an external fixation device comprised of four main parts: An inner rail, two outer rails, two upper side arms, and two lower side arms. It utilizes short or long cannulated nails and is stored preassembled.

Intended Use: The Synthes (USA) 2nd Generation Pelvic C-Clamp is intended for emergency stabilization of sacrum fractures or disruptions of the sacroiliac joint with associated circulatory instability.

Substantial Equivalence: Documentation is provided which demonstrates the Synthes (USA) 2nd Generation Pelvic C-Clamp to be 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

Synthes (USA)
c/o Ms. Angela Silvestri
Director, Regulatory Affairs
1301 Goshen Parkway
West Chester, PA 19380

AUG 2 4 2007

Re: K071476
Trade/Device Name: 2nd Generation Pelvic C-Clamp
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: JEC
Dated: August 3, 2007
Received: August6, 2007

Dear Ms. Silvestri:

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.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SYNTHES®

2.0 **Indications for Use**

510(k) Number (if known): K071476

Device Name: Synthes (USA) 2nd Generation Pelvic C-Clamp

Indications for Use:

The Synthes (USA) 2nd Generation Pelvic C-Clamp is intended for emergency stabilization of sacrum fractures or disruptions of the sacroiliac joint with associated circulatory instability.

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 K071746