K000120

SYNTHES®

AUG 2 4 2000

3.0 Summary of Safety and Effectiveness Information

SPONSOR:	Synthes (USA) 1690 Russell Road Paoli, PA 19301 (610) 647-9700 Contact: Angela Silvestri
DEVICE NAME:	Synthes Sacral Bar System
CLASSIFICATION:	21 CFR 888.3040 Smooth or threaded metallic bone fixation fastener.
PREDICATE DEVICES:	Zimmer Threaded Sacral Rod Synthes Threaded Bolt
DEVICE DESCRIPTION:	The Synthes Sacral Bar System consists of a threaded bar, washers, and nuts. The bars are fully threaded. One end of the bar has a trocar point to guide the bar through pre-drilled holes. The bars are available in lengths ranging from 120 to 260 mm, in 10 mm increments. The washers that are used with this system are oval shaped and are designed to slide freely along the bars. Both rounded and straight nuts are provided with this system; the rounded nuts mate with the washers to create compression, while the straight nuts are then added to wedge against the rounded nuts to maintain compression.
INTENDED USE:	The Synthes Sacral Bar System is intended for fixation of fractures of the posterior pelvis, in areas of the posterior superior iliac spine and posterior inferior iliac spine, for sacral fractures and fracture-dislocations of the sacro-iliac joint.
MATERIAL:	Implant quality stainless steel.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 4 2000

Ms. Angela Silvestri
Manager, Regulatory Affairs
Synthes U.S.A.
1690 Russell Road
Paoli, Pennsylvania 19301

Re: K001720
Trade Name: Sacral Bar System
Regulatory Class: II
Product Code: JDW
Dated: June 5, 2000
Received: June 6, 2000

Dear Ms. Silvestri:

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 control provisions of the Act. The general control 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,

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

SYNTHES®

2.0 Indications for Use Statement

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510(k) Number (if known): K001720

Device Name: Synthes Sacral Bar System

INDICATIONS/CONTRAINDICATIONS:

The Synthes Sacral Bar System is intended for fixation of fractures of the posterior pelvis, in areas of the posterior superior iliac spine and posterior inferior iliac spine, for sacral fractures and fracture-dislocations of the sacro-iliac joint.

(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 Devices
510(k) Number K001720

Prescription Use X OR Over-The-Counter Use_____
(Per 21 CFR 801.109)