MAY 3 0 2003

K03/508
page 1 of 1

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

SPONSOR:	Synthes (USA) 1690 Russell Road Paoli, PA 19301 (610) 647-9700 Contact: Lisa M. Boyle
DEVICE NAME:	Synthes (USA) Sternal Reconstruction System
CLASSIFICATION:	Class II § 21 CFR 888.3010: Cerclage, fixation Class II § 21 CFR 888.3030: Plate, fixation, bone Class II § 21 CFR 888.3040: Screws, fixation, bone
PREDICATE DEVICE:	Synthes Cerclage Wire (Pre-76)
DEVICE DESCRIPTION:	The Synthes Sternal Reconstruction System is a cable-based system comprised of stainless steel cable, cannulated screws and plates. The system is designed to allow for multiple sternal repair and reconstruction options. It can be used as follows: • Cable only • Cable and cannulated screws • Cable, cannulated screws, and plates
INTENDED USE:	Synthes (USA) Sternal Reconstruction System is intended for use in sternal repair and reconstruction.
SUBSTANTIAL EQUIVALENCE:	Comparative information presented supports substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 3 0 2003

Ms. Lisa Boyle
Regulatory Associate
Synthes USA
1690 Russell Road
Post Office Box 1766
Paoli, PA 19301

Re: K031508
Trade/Device Name: Syntehes (USA) Sternal Reconstruction System
Regulation Number: 21 CFR 888.3010, 888.3030 and 888.3040
Regulation Name: Bone fixation cerclage, Single/multiple component metallic bone fixation appliances and accessories and Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: JDQ, HRS, HWE
Dated: May 12, 2003
Received: May 14, 2003

Dear Ms. Boyle:

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): K031508

Device Name: Synthes (USA) Sternal Reconstruction System

Indications:

Synthes (USA) Sternal Reconstruction System is intended for use in sternal repair and reconstruction.

(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)

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

510(k) Number K031508