MAY 1 1 1998

K981372

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

SPONSOR	Synthes (USA) 1690 Russell Road Paoli, PA 19301 (610) 647-9700 Contact: Angela Silvestri
COMMON OR USUAL NAME:	Bone Plate and Bone Screw
DEVICE CLASSIFICATION	Class II, 21 CFR 888.3030 and 888.3040
PREDICATE DEVICE:	Synthes PC-Fix
DESCRIPTION:	The Synthes 3.0 mm PC-Fix™ is a plate and screw system. The plate shares normal weight-bearing forces/load with the fixed fractured bone, and is fixed to the bone with locking screws, bridging the fracture as it heals. The plate neutralizes most of the torsional, shear and bending forces that would otherwise be transferred to the fracture site. This system is designed to be less invasive, as stripping of the periosteum is not recommended; reduce the risk of infection, refracture, implant failure, and loss of reduction (and subsequent complications); allow for early weight-bearing and early implant removal; and reduce surgery time (no screw measuring, simpler procedure). The plates are available as Straight, T-shaped, and Reconstruction in commercially pure titanium. The screws are available in titanium alloy.
INTENDED USE:	The Synthes 3.0 mm PC-Fix™ is a long bone and small bone plate and screw system, intended to treat fractures of various bones, including the radius, ulna, distal tibia, pelvis, clavicle, fibula, humerus, and scapula.
MATERIAL:	The 3.0 mm PC-Fix™ plates are manufactured from commercially pure titanium, while the screws are manufactured from a titanium alloy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 1 1998

Ms. Angela J. Silvestri
Manager, Regulatory Affairs
Synthes®
1690 Russell Road
Post Office Box 1766
Paoli, Pennsylvania 19301

Re: K981372
Trade Name: 3.0mm PC-FIX™ System
Regulatory Class: II
Product Codes: HWC and HRS
Dated: April 15, 1998
Received: April 16, 1998

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 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. Note that labeling or otherwise promoting a device for pedicular screw fixation/attachment would cause the device to be adulterated under 501(f)(1) of the Act. This device, if intended for use in pedicular screw fixation/attachment, would be found not substantially equivalent and would be a class III device under Section 513(f) of the Act. Class III devices are required to have an approved premarket approval (PMA) application prior to marketing. Accordingly:

1. The package insert must prominently state that the device is intended for the specific use(s) described in the enclosure only; and

2. You may not label or in any way promote this device for pedicular screw attachment to, or fixation of the cervical, thoracic or lumbar vertebral column. If this device is a screw with outer diameters of 3 mm - 10 mm and overall lengths of 10 mm - 75 mm inclusively, the package insert must include the following statement, "**WARNING:** This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine." Any pedicular screw fixation/attachment to the cervical, thoracic or lumbar vertebral column of this device is considered investigational and may only be investigated as a significant risk device in accordance with the investigational device exemption (IDE) regulations under 21 CFR, Part 812. All users of the device for pedicular screw fixation/attachment must receive approval from their respective institutional review boards (IRBs) and the Food and Drug Administration (FDA) prior to conduct of the investigation.

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 immediately. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and 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 (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 and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K981372

Device Name: Synthes (USA) 3.0 mm PC-Fix ™ System

Indications for use:

The Synthes 3.0 mm PC-Fix™ is a long bone and small bone plate and screw system, intended to treat fractures of various bones, including the radius, ulna, distal tibia, pelvis, clavicle, fibula, humerus, and scapula.

(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 K981372

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