

Attachment VI:**Summary of Safety and Effectiveness Information
[510(k) Summary]**

SUBMITTER Synthes (USA)
1690 Russell Road
Paoli, PA 19301
(610) 647-9700

Contact: Sheri L. Musgnung

DEVICE NAME: Synthes Cerclage Positioning Pin

COMMON OR USUAL NAME Smooth or thread metallic bone fixation fastener

DEVICE CLASSIFICATION: Class II, 21 CFR 888.3040

PREDICATE DEVICE: Synthes Wire Mount (K953777)

DESCRIPTION: The design of the cerclage positioning pin is an oval body with a hole running perpendicular to the long axis (for use in compression holes), and has a stud protruding from the bottom. By placing the post through the top of the dynamic compression screw hole into a pre-drilled hole in cortical bone a stable structure is created for cerclage wire or cable fixation. The wire or cable is passed around the bone, through the Cerclage Positioning Pin hole above the outer plate surface, and then the wire is twisted or cable is crimped for final securement.

INTENDED USE: Synthes Cerclage Positioning Pin is intended for use with cerclage monofilament wire and multifilament cable to augment fracture stabilization with plates used in long bone fixation when the use of screws is contraindicated, as in the presence of intramedullary implants.

The Cerclage Positioning Pin is designed for use in dynamic compression screw holes that accept a 4.5 mm bone screw. The Cerclage Positioning Pin (and cerclage wire or cable) can be used with a variety of Synthes plates.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

NOV - 2 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Sheri L. Musgnung
Regulatory Affairs Specialist
Synthes USA
1690 Russell Road
Paoli, Pennsylvania 19301

Re: K992891
Trade Name: Synthes Cerclage Positioning Pin
Regulatory Class: II
Product Code: JDQ
Dated: August 26, 1999
Received: August 27, 1999

Dear Ms. Musgnung:

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.

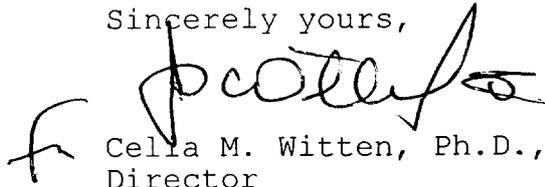
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 - Ms. Sheri L. Musgnung

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 (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



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



2.0 Indications for Use Statement

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510(k) Number (if known): K992891

Device Name: Synthes Cerclage Positioning Pin

Indications For Use:

Synthes Cerclage Positioning Pin is intended for use with cerclage monofilament wire and multifilament cable to augment fracture stabilization with plates used in long bone fixation when the use of screws is contraindicated, as in the presence of intramedullary implants.

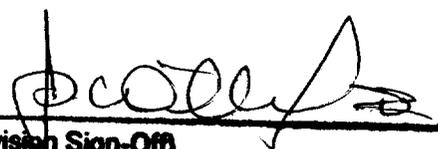
The Cerclage Positioning Pin is designed for use in dynamic compression screw holes that accept a 4.5 mm bone screw. The Cerclage Positioning Pin (and cerclage wire or cable) can be used with a variety of Synthes plates.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR Over-The-Counter Use _____



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K992891