K984377

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

SYNTHES (U.S.A.)
1690 Russell Road
Paoli, PA 19301

(610) 647-9700
Contact: Jonathan Gilbert
01/08/99

Device: ***SYNTHES Spine* CerviFix System** consisting of rods, plate/rods, hooks, bone screws, parallel connectors and set screws. These components are manufactured from the titanium alloy TiAlNb (ASTM F1295). The bone screws are composed of commercially pure grade 4 Titanium (ASTM F67).

The CerviFix System is intended to provide stabilization to promote fusion of the cervical spine and occipital-cervical junction (occiput – T3) for the following indications:

- DDD (neck pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies)
- spondylolisthesis
- spinal stenosis
- fracture/dislocation
- atlanto-axial fracture with instability
- occipital-cervical dislocation
- revision of previous cervical spine surgery
- tumors

The screws are limited to occipital fixation only.

The CerviFix System can also be linked to the Synthes Posterior Universal Spine System using the 3.5/6.0mm parallel connectors from that system.

The rods are 3.5mm in diameter and are offered in four lengths, 80, 120, 240 and 300mm. The plate/rod is a 3.5 mm or 6.0 mm diameter rod that transitions into a 3.5mm reconstruction plate at the opposite end. Hooks are available in both a left and right configuration to allow bilateral placement of the hook/rod or plate/rod/hook construct. The occipital bone screws are provided in the following configurations: a 3.2mm cortex screw, a 3.5mm cancellous screw, or a 4.0mm cancellous screw.

The device functions as follows: For non occipitocervical fusion, the end of the rod, cut to an appropriate length, is inserted into the rod opening of the hooks and loosely tightened into position with the set screws included in the hooks. The construct is then positioned under the laminae of the spinal segments to be instrumented. Once the construct is compressed together, the set screws are locked down to the rod. For occipitocervical fusion, the plate/rod is bent and cut to an appropriate length. The plate portion of the implant is fixed to the occiput with screws and the rod portion is attached to the cervical spine with hooks. Hooks are available in both right and left opening configurations to allow bilateral placement of the hook/rod construct.

The construct can also be linked to the 6.0mm diameter rods of the Universal Spine System (USS) using 3.5mm/6.0mm parallel connectors.

Mechanical testing was previously performed in accordance with ASTM standard F1717. This testing documented both static and fatigue performance characteristics and demonstrated that the performance characteristics satisfy the requirements of posterior occipitocervical and upper thoracic (Occiput-T3) fixation.

Material composition is identical to numerous other Synthes Spinal products that have been cleared via the 510(k) process. The methods for use and instrumentation to implant this system is similar to that of the Synthes CerviFix and the Occipital-Cervical Plate/Rod and Hook systems.

Based on the above, the *Synthes Spine* CerviFix System is substantially equivalent to components cleared in previously cleared Synthes premarket submissions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 21 1999

Mr. Jonathan M. Gilbert
Senior Regulatory Affairs Associate
Synthes Spine
Post Office Box 0548
1690 Russell Road
Paoli, Pennsylvania 19301

Re: K984377
Synthes CerviFix System – additional components
Regulatory Class: II
Product Code: KWP
Dated: December 2, 1998
Received: December 3, 1998

Dear Mr. Gilbert:

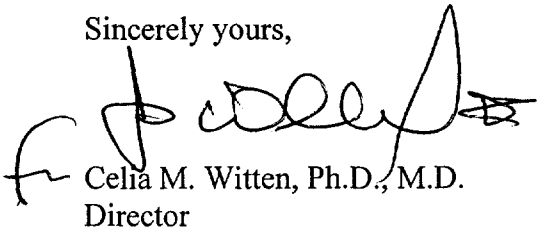
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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). 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 (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 requirements, 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" (21CFR 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/dsma/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

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510(k) Number (if known): NA K984377

Device Name: Synthes CerviFix System

Indications for Use:

The CerviFix System is intended to provide stabilization to promote fusion of the cervical spine and occipital-cervical junction (occiput – T3) for the following indications:

- DDD (neck pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies)
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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use _____(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K984377