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
6/10/99

Device: Synthes CerviFix System consists of rods, plate/rods, hooks, clamps and bone screws. The hooks, clamps, rods and plate/rods are composed of the titanium alloy Ti6Al7Nb (ASTM F1295). The screws are composed of commercially pure grade 4 Titanium (ASTM F67).

Indications for Use:

Hooks, Plate/Rods, Rods and Screws

When intended to promote fusion of the cervical spine and occipitocervical junction (occiput-T3), the plate/rod, rod, hook and screw (3.2mm cortical, 3.5mm and 4.0mm cancellous) components of the Synthes CerviFix System are indicated for the following:

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

When used to treat these cervical and occipitocervical conditions, these screws are limited to occipital fixation only.

Hooks and Rods

The rod and hook components are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C1-T3) spine.

Rods, Clamps and Screws

The rods, clamps and screws are intended to promote fusion following reduction of fracture/dislocation or trauma in the upper thoracic spine (T1-T3)

The use of these screws (3.5mm cancellous, 4.0mm cancellous, 4.0mm and 4.35 expansionhead) is limited to placement in T1 -T3 in treating thoracic conditions only. They are not intended to be placed in or treat conditions involving the cervical spine.

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

This system is provided non-sterile; moist heat sterilization is recommended. Based on the above, the Synthes CerviFix System is substantially equivalent to itself.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 1 1999

Mr. Jonathan Gilbert
Senior Regulatory Affairs Associate
SYNTHES SPINE
P.O. Box 0548
1690 Russell Road
Paoli, Pennsylvania 19301

Re: K990965
Trade Name: Synthes CerviFix System
Regulatory Class: II
Product Code: KWP and MNI
Dated: June 10, 1999
Received: June 15, 1999

Dear Mr. Gilbert:

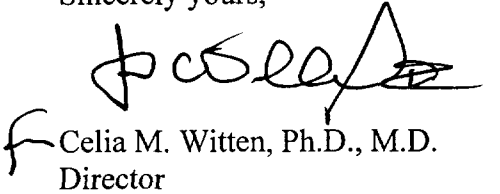
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 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,



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): K990965

Device Name: Synthes CerviFix System

Indications for Use:

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

Prescription Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K990965