K030377 p1/

8.4.1 ATTACHMENT IV – 510K SUMMARY OF SAFETY AND EFFECTIVENESS DEVICE

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Synthes CerviFix® consists of rods, plate/rods, hooks, clamps, screws, nuts, transconnectors and transverse bars. The implants are composed of Titanium or Stainless Steel.

INDICATIONS

Indications for Use:
The CerviFix® System is 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, Screws and Nuts
The rods, clamps, screws and nuts are intended to promote fusion following reduction of fracture/dislocation or trauma in the upper thoracic spine (T1-T3).

The use of these screws (3.5 mm, 4.0 mm cancellous and 3.5 mm, 4.2 mm cortex) 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 Synthes *CerviFix*™ System can also be linked to the Synthes Universal Spinal System using the 3.5 mm/6.0 mm parallel connectors from that system, and via the CerviFix tapered rods using lamina hooks, transverse process hooks, pedicle hooks, 4.2 mm screws, and the 5.0 mm/ 6.0 mm parallel connector.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 0 6 2003

Ms. Vikki Hoffman
Senior Regulatory Affairs Associate
Synthes Spine
Post Office Box 0548
1690 Russell Road
Paoli, Pennsylvania 19301

Re: K030377
Trade/Device Name: Synthes CerviFix™ System
Regulatory Number: 21 CFR 888.3070, 21 CFR 888.3050
Regulation Name: Pedicle screw spinal system, Spinal interlaminal fixation orthosis
Regulatory Class: II
Product Code: MNI, KWP
Dated: February 4, 2003
Received: February 5, 2003

Dear Ms. Hoffman:

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.

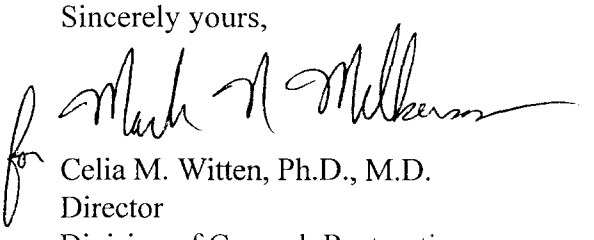
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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. 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,



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

page 1 of 2

8.2 ATTACHMENT II – INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K030377

Device Name: Synthes CerviFix®

Indications for Use:
The CerviFix® System is 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
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Hooks and Rods
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Rods, Clamps, Screws and Nuts
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The use of these screws (3.5 mm, 4.0 mm cancellous and 3.5 mm, 4.2 mm cortex) 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.

for Mark N Milhous

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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 _____ OR Over-The-Counter Use_____
(Per 21 CFR § 801.109)

for Mark N Milhern

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