

APR 16 1998

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April 3, 1998**Summary of Safety and Effectiveness Information
[510(k) Summary]**SYNTHES (U.S.A.)
1690 Russell Road
Paoli, PA 19301(610) 647-9700
Contact: Barry E. Sands
1/28/98

Device: SYNTHES Spine Posterior Cervical/Thoracic Hook/Rod System compared to the AME Halifax Interlaminar Clamp System (K850039 & K062314).

The Synthes Posterior Cervical/Thoracic Hook/Rod System consists of rods, clamps and set screws. These components are manufactured from the titanium alloy TiAlNb (ASTM F1295). The Posterior Cervical/Thoracic Hook/Rod System is intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C1-T3) spine.

Manual surgical instruments that will be marketed with this system include Rod Bending Plier for 3.5 rods, 2.5mm Hex screwdriver, and holding forcep.

The rods are 3.5mm in diameter and are offered in lengths of 80 and 240mm. Hooks are available in both a left and right configuration to allow bilateral placement of the hook/rod construct.

Mechanical testing was performed in accordance with ASTM standard F1717. This testing documented both static and fatigue performance characteristics. This testing clearly demonstrated that the performance characteristics satisfy the requirements of posterior cervical and upper thoracic (C1-T3) fixation.

The SYNTHES Spine Posterior Cervical/Thoracic Hook/Rod System is indicated for the same clinical indications as that of the AME Halifax Interlaminar Clamp System. The levels of use to T3 do not have a significant effect on safety or effectiveness. This due to the fact that loading in these areas is not significantly different when compared to the cervical area. In addition, other systems such as the LIBERTY system by Sofamor Danek are cleared in the T1-T3 region.

Material composition is identical to numerous other Synthes Spinal products that have been cleared via the 510(k) process. The surgical technique and instrumentation to implant this system is the same as that of the Synthes USS Hook/Rod systems.

This system is provided non-sterile; moist heat sterilization is recommended.

Based on the above, the SYNTHES Spine Posterior Cervical/Thoracic Hook/Rod System is substantially equivalent to the AME Halifax Interlaminar Clamp System.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 16 1998

Mr. Barry E. Sands
Manager, Regulatory Affairs
SYNTHES Spine
P.O. Box 0548
1690 Russell Road
Paoli, Pennsylvania 19301

Re: K980358
SYNTHES Spine Posterior Cervical/Thoracic Hook/Rod System
Regulatory Class: II
Product Code: KWP
Dated: January 28, 1998
Received: January 29, 1998

Dear Mr. Sands:

We have reviewed your Section 510(k) notification of intent to market the device system referenced above and we have determined the device system is substantially equivalent (for the indications for use stated in the enclosure) to device systems marketed in interstate commerce prior to May 28, 1976 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 your device system subject to the general controls provisions of the Act and the limitations identified below.

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 this device system for pedicular screw fixation/attachment would cause the device system to be adulterated under 501(f)(1) of the Act.

FDA identifies that any device system, if intended for use in pedicular screw fixation/attachment, except for some limited indications, 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. You may not label or in any way promote this device system for pedicular screw attachment to, or fixation of the cervical, thoracic or lumbar vertebral column. Therefore, in order to prevent off-label promotion, the

package insert must include the following statement,
"**WARNING:** This device system is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.";

2. All labeling for this device system, including the package label, must state that there are labeling limitations. The package insert must prominently state that the device system is intended for the specific use(s) described in the enclosure only; and
3. Pedicular screw fixation/attachment to the cervical, thoracic or lumbar vertebral column, except for limited indications, of any device system 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 system for pedicular screw fixation/attachment must receive approval from their respective institutional review boards (IRBs) and the Food and Drug Administration (FDA) prior to conducting an investigation.

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 pre-market 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.

FDA advises that the use of the subject device system and/or device components with any other device components but those identified in this 510(k) would require submission of a new 510(k) providing documentation of design, material, and labeling compatibility between the device components. Mechanical testing of a spinal system consisting of the subject device components and other device components, whether yours or other manufacturers', may also be required.

Page 3 - Mr. Barry E. Sands

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): NA K980358

Device Name: Posterior Cervical/Thoracic Hook/Rod System

Indications for Use:

The Posterior Cervical/Thoracic Hook/Rod System is intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C1-T3) spine.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription X
(Per 21 CFR 801.109)

OR

Over-the-Counter Use _____



(Division Sign-Off)
Division of General Restorative Devices K980358
510(k) Number _____