

MAY 11 1998

K980928

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

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

(610) 647-9700  
Contact: Barry E. Sands  
1/28/98

Device: **SYNTHESES Spine Universal Spinal Hook, Rod, Pedicle/Sacral Screw Fixation System** compared to the Liberty Posterior Spinal System (K964254) and the Titanium Spinal Rod System (K970635).

The **Synthes Universal Spinal Hook, Rod, Pedicle/Sacral Screw Fixation System** currently consists of rods, hooks, clamps and screws. These components were previously cleared in K951626, K951794, K962608, K963045, K963357, and K964416. This 510(k) submission is extending the region of the posterior spine in which the USS hook and rods may be used (i.e., from T8-S2 to T4-S2). In addition to these components Synthes is adding a new parallel rod connector. The connector is intended to allow a rod (3.5mm) to rod (6mm) connection with the Posterior Cervical/Thoracic Hook/Rod System. The **Universal Spinal Hook, Rod, Pedicle/Sacral Screw Fixation System** is indicated for the following:

When used as a posterior pedicle screw fixation system, the Synthes Universal Spinal Hook, Rod and Pedicle/Sacral Screw Fixation System is intended for patients with severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar-first sacral (L5-S1) vertebral joint; who are receiving fusions using autogenous bone graft only; who are having the device fixed or attached to the lumbar and sacral spine; and who are having the device removed after the development of a solid fusion mass.

When used as a posterior, non-pedicle screw fixation system, the Universal Spinal Hook, Rod and Pedicle/Sacral Screw Fixation System is also intended for scoliotic, lordotic, or kyphotic deformities (such as scoliosis, Scheuermann's disease); degenerative disk disease (back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), and fractures of the posterior thoracolumbar spine (levels T4-S2). In addition, when using the parallel rod connector, the USS can be connected to the Posterior Cervical/Thoracic Hook/Rod System.

The overall levels of fixation are T4-S2.

Manual surgical instruments that will be marketed with this system will be the same as that currently marketed with the **Universal Spinal Hook, Rod, Pedicle/Sacral Screw Fixation System (USS)**.

Mechanical testing was performed in accordance with ASTM standard F1717. This testing documented both static and fatigue performance characteristics of the USS system, when connected via the parallel rod connector, to the Posterior Cervical/Thoracic Hook/Rod System. This testing clearly demonstrated that the performance characteristics satisfy the requirements of upper thoracic (T1-T8) fixation.

Material composition of the parallel rod connector is TiAINb (ASTM F1295) and is identical to numerous other Synthes Spinal products that have been cleared via the 510(k) process. The remaining components of the USS system are composed of the same materials described within their respective 510(k)s. The surgical technique and instrumentation to implant this system is the same as that of the **Synthes USS**.

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

Based on the above, the **SYNTHES Spine Universal Spinal Hook, Rod, Pedicle/Sacral Screw Fixation System** is substantially equivalent to the Liberty Posterior Spinal System (K964254) and the Titanium Spinal Rod System (K970635).



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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

Re: K980928  
Trade Name: Universal Spinal Hook, Rod,  
Pedicle/Sacral Screw Fixation System  
Regulatory Class: II  
Product Codes: KWP and MNH  
Dated: March 10, 1998  
Received: March 11, 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). This decision is based on your device system being found equivalent only to similar device systems labeled and intended for patients: (a) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar - first sacral (L5-S1) vertebral joint; (b) who are receiving fusions using autogenous bone graft only; (c) who are having the device fixed or attached to the lumbar and sacral spine; and (d) who are having the device removed after the development of a solid fusion mass. 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 for indications other than severe spondylolisthesis, as described above, would cause the device system to be adulterated under 501(f)(1) of the Act.

This device system, when intended for pedicular screw fixation/attachment to the spine for indications other than severe spondylolisthesis, as described above, is 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. All labeling for this device, including the package label, must state that there are labeling limitations. The package insert must prominently state that the device system using pedicle screws is intended only for patients: (a) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar - first sacral (L5-S1) vertebral joint; (b) who are receiving fusions using autogenous bone graft only; (c) who are having the device fixed or attached to the lumbar and sacral spine; and (d) who are having the device removed after the development of a solid fusion mass.
2. You may not label or in anyway promote this device system for pedicular, screw fixation/attachment to the cervical, thoracic or lumbar vertebral column for intended uses other than severe spondylolisthesis, as described above. The package insert must include the following statements:

**WARNINGS:**

- When used as a pedicle screw system, this device system is intended only for grade 3 or 4 spondylolisthesis at the fifth lumbar - first sacral (L5-S1) vertebral joint.
- The screws of this device system are not intended for insertion into the pedicles to facilitate spinal fusions above the L5-S1 vertebral joint.
- Benefit of spinal fusions utilizing any pedicle screw fixation system has not been adequately established in patients with stable spines.
- Potential risks identified with the use of this device system, which may require additional surgery, include:
  - device component fracture,
  - loss of fixation,
  - non-union,
  - fracture of the vertebra,
  - neurological injury, and
  - vascular or visceral injury.

See Warnings, Precautions, and Potential Adverse Events sections of the package insert for a complete list of potential risks.

3. Any pedicular screw fixation/attachment for intended uses other than severe spondylolisthesis, as described by item 1, for this device 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 for pedicular screw fixation/attachment for intended uses other

than severe spondylolisthesis, as described above, must receive approval from their respective institutional review boards (IRBs) and the Food and Drug Administration (FDA) prior to conducting an investigation.

4. Any previous warning statements identified as part of previous 510(k) clearances or required by OC/Labeling and Promotion which stated that a component/system was not approved for screw fixation into the pedicles of the spine must be replaced by the warnings of items 1 and 2 above.

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.

FDA advises that the use of your device system 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 those of other manufacturers, may also be required.

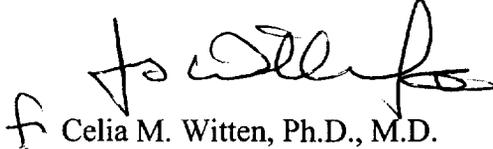
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification immediately. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the 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

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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,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is stylized with a large initial "C" and a long horizontal flourish at the end.

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

Device Name: Universal Spinal Hook, Rod, Pedicle/Sacral Screw Fixation System

Indications for Use:

When used as a posterior pedicle screw fixation system, the Synthes Universal Spinal Hook, Rod and Pedicle/Sacral Screw Fixation System is intended for patients with severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar-first sacral (L5-S1) vertebral joint; who are receiving fusions using autogenous bone graft only; who are having the device fixed or attached to the lumbar and sacral spine; and who are having the device removed after the development of a solid fusion mass.

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The overall levels of fixation are T4-S2.

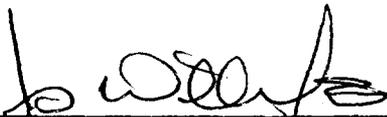
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-the-Counter Use \_\_\_\_\_

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K980928