

AUG 4 1998

K980761

## 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  
2/19/1998

Device: *SYNTHES Spine Pediatric Rod System* compared to the Acromed ISOLA Pediatric Components (K962984).

The *SYNTHES Spine Pediatric Rod System* consists of rods, clamps and screws. The screws are composed of commercially pure grade 4 Titanium (ASTM F67). The clamps and rods are composed of the titanium alloy TAN (ASTM F1295).

The rod is provided in four lengths, 80, 120, 240 and 300mm. The rod diameter is 3.5mm. The clamps are designed to connect the 3.5mm rods and screws utilized for this system. The screws are provided in the following configurations: 3.5mm cancellous screw, a 4.0mm cancellous screw, or a 4.0mm or 4.35mm expansion screw with 1.8mm locking screw.

The device functions as follows: The end of the rod, cut to an appropriate length, is inserted into the rod opening of the clamps and loosely tightened into position with the set screws included in the clamps. The awl is used to open the cortex. The K-wire is used to manually extend the hole. The length of screw is determined with the depth gauge, then the hole is tapped. The screw is inserted through the clamp at the desired level. The set screws are then locked down to the rod.

The *SYNTHES Spine Pediatric Rod System* is a pedicle screw fixation system for use in grade 3 or 4 spondylolisthesis at the fifth lumbar - first sacral vertebral joint (L5-S1) utilizing autologous bone graft and intended to be removed after solid fusion is attained. The *SYNTHES Spine Pediatric Rod System* is intended for pediatric patients with a body weight of 50lbs or less.

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

Based on the above, the *SYNTHES Spine Pediatric Rod System* is substantially equivalent to the Acromed ISOLA Pediatric Components.



AUG 4 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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

Re: K980761  
SYNTHES Spine Pediatric Rod System  
Regulatory Class: Unclassified  
Product Code: MNH  
Dated: June 9, 1998  
Received: June 10, 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.

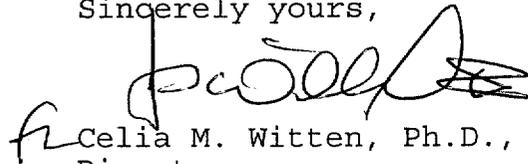
FDA advises that the use of your device system with any other device components but those identified in this 510(k) would require submission of a new 510(k) providing documentation of design, material, and labeling compatibility between the device components. Mechanical testing of a spinal system consisting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

Page 4 - 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,

  
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 K980761

Device Name: SYNTHES Spine Pediatric Rod System

Indications for Use:

When labeled for pedicle screw fixation, the Pediatric Rod System is intended for use in grade 3 or 4 spondylolisthesis at the fifth lumbar - first sacral vertebral joint (L5-S1) utilizing autologous bone graft and intended to be removed after solid fusion is attained. The SYNTHES Spine Pediatric Rod System is intended for pediatric patients with a body weight of 50lbs or less.

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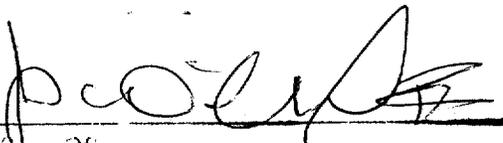
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X  
(Per 21 CFR 801.109)

OR

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

  
\_\_\_\_\_  
(Division) \_\_\_\_\_  
Division \_\_\_\_\_  
510(k) Number K980761