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

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

(610) 647-9700  
Contact: Jon Gilbert  
4/30/99

Device: Synthes Pediatric Rod System consists of rods, clamps, nut 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 Starlock clamps, Starlock screws and nut are composed of the titanium alloy TAN (ASTM F1295).

The 3.5mm rod is provided in four lengths, 80, 120, 240 and 300mm. 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, 4.0mm or 4.35mm expansion screw with 1.8mm locking screw, 3.5mm and 4.0mm cancellous and 3.5 cortical StarLock screws, medial, lateral, neutral, and upgoing, and offset StarLock clamps. Manual surgical instruments are included to implant components of this system.

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.

When the StarLock components are used with the 3.5 mm rod, the following assembly steps are followed after the screw hole is prepared and proper screw length determined: A StarLock screw is inserted at the desired level. A StarLock clamp is placed onto the screw and a StarLock nut is loosely threaded onto the head of the screw. The remaining screws, clamps and nuts are inserted in the same manner. A 3.5mm 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 with the clamps. After final adjustment of the construct, the set screws are locked down to the rod and the nuts are fully tightened.

The Synthes 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 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 Pediatric Rod System is substantially equivalent to K980761.



JUN 2 1999

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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

Re: K991552  
Trade Name: Synthes Pediatric Rod System  
Regulatory Class: II  
Product Code: MNH  
Dated: April 30, 1999  
Received: May 3, 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.

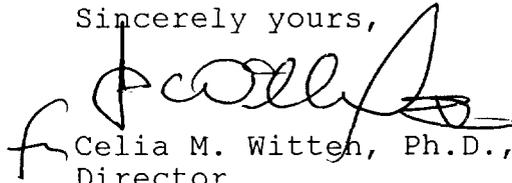
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 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.

Page 2 - Mr. Jonathan Gilbert

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 (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

Synthes Pediatric Rod System  
Special 510(k) Premarket Notification – Device Line Extension

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510(k) Number (if known): ~~NA~~ K991552

Device Name: Synthes 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 Pediatric Rod System is intended for pediatric patients with a body weight of 50lbs or less.

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

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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 K991552