WRIGHT
MEDICAL TECHNOLOGY, INC.
5677 AIRLINE ROAD
ARLINGTON, TN 38002
901-867-9971

K980496

APR 14 1998

510(k) Summary

Contact Person:	Lynne Witkowski
Date Prepared:	March 31, 1998
Device Name:	Rod-To-Rod Coupler
System Name:	Versalok Posterior Spinal Fixation System
Predicate Device:	DePuy Motech MOSS Miami Spinal System, SYNTHES (USA) Universal Modular Spinal System

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92.

Intended Use

A construct with screws attached to the pedicles of the lumbar and sacral spine (L3 to S1) and autogenous bone graft may be used only for the treatment of severe spondylolisthesis (Grade 3 and Grade 4) at the fifth lumbar - first sacral (L5-S1) vertebral joint (see warnings below). The device is intended to be implanted using a posterior surgical approach and removed after the development of a solid fusion mass.

When not used as a pedicle screw fixation system, various combinations of the Versalok Posterior Spinal Fixation System components are also indicated to provide temporary stability of the thoracic, thoracolumbar, or lumbar spine (T1 to S1) during bony fusion healing secondary to:

1. Unstable spinal fractures (such as fracture dislocations) or instability secondary to spinal tumors;
2. Degenerative disk diseases of the spine (defined as back pain of diskogenic origin with degeneration of the disk confirmed by history and radiographic studies);
3. Spinal curvatures (such as idiopathic scoliosis, neuromuscular scoliosis/kyphoscoliosis with associated paralysis or spasticity, and secondary to spinal fractures) which are:
   - Progressive, despite other forms of treatment,
   - Detrimental to cardiopulmonary function,
   - Interfering with spinal mechanics or causing severe back pain, or
   - Cosmetically unacceptable, progressive, and painful.

The system is intended to provide temporary maintenance and support of the correction during the time normally needed for the fusion mass to mature. Use of spinal fixation instrumentation in children has been reported. Children should have adequate bony and soft tissue maturity to undergo implantation but need not have reached skeletal maturity.

Description

The coupler is designed to form a transverse connection between spinal rods in a spinal construct in order to increase the torsional stiffness of the construct.

Materials

All the components are made from stainless steel.

Testing Summary

Submitted testing demonstrates that the Rod-To-Rod Coupler fatigue performance is comparable to a predicate device and adequate for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 14 1998

Ms. Lynne Witkowski
Regulatory Affairs Associate
Wright Medical Technology, Inc.
5677 Airline Road
Arlington, Tennessee 38002

Re: K980496
Rod-to-Rod Couplers - part of the Versalok Posterior Spinal Fixation System (K950074 and K961572)
Regulatory Class: II
Product Codes: MNH and KWP
Dated: February 6, 1998
Received: February 9, 1998

Dear Ms. Witkowski:

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 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 Stephen Rhodes

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

Wright Medical Technology, Inc.
Premarket Notification K980496
Wright Medical Technology Rod-To-Rod Coupler

C. Indications for Use of the Device

510(k) Number (if known):

Device Name: Rod-To-Rod Coupler
System Name: Versalok Posterior Spinal Fixation System

Indications for Use:
The Rod-To-Rod Coupler is intended to form a transverse connection between spinal rods in a spinal construct in order to increase the torsional stiffness of the construct.

A construct with screws attached to the pedicles of the lumbar and sacral spine (L3 to S1) and autogenous bone graft may be used only for the treatment of severe spondylolisthesis (Grade 3 and Grade 4) at the fifth lumbar - first sacral (L5-S1) vertebral joint (see warnings below). The device is intended to be implanted using a posterior surgical approach and removed after the development of a solid fusion mass.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X **Or** **Over-the-Counter Use**
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Stephen Rhodes
(Division Sign-Off)
Division of General Restorative Devices K980496
510(k) Number