

DEC 22 1998

## Thoracolumbar Spinal System

**Summary of Safety and Effectiveness**K983899  
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**SUBMITTER:** United States Surgical Corporation  
150 Glover Avenue  
Norwalk, CT 06856

**CONTACT PERSON:** Sharon L. Murphy

**DATE PREPARED:** September 29, 1998

**CLASSIFICATION NAME:** Spinal Intervertebral Body Fixation Orthosis  
Spinal Interlaminar Fixation Orthosis  
Spondylolisthesis Spinal Fixation Device System

**COMMON NAME:** Spinal Rod System

**PROPRIETARY NAME:** Thoracolumbar Spinal Rod System

**PREDICATE DEVICES:** USSC's Surgical Dynamics™ Thoracolumbar Spinal Rod  
(Empower) System – K954696, K965224

**DEVICE DESCRIPTION:** The Thoracolumbar Spinal Rod System consists of stainless steel rods attached to the spinal column through the use of interlaminar hooks and/or screws. Crossbars may be used to connect rods to rods to provide a more rigid construct, as well as screws to rods and hooks to rods.

**INTENDED USE:** ***Non-Pedicle Screw Fixation***

When used as an anterior spinal system the Thoracolumbar Spinal Rod System is intended for the treatment of DDD (degenerative disc disease defined as back pain of discogenic origin with degeneration of the disc confirmed by history or radiographic studies), pseudoarthrosis, stenosis, deformities (scoliosis, kyphosis, lordosis), spondylolisthesis, fracture, previous failed fusion, or tumor resection. The Thoracolumbar Spinal Rod System is limited to non-cervical use.

When used as a posterior, non-pedicle spinal system (consisting of hooks and sacral/iliac screws), the Thoracolumbar Spinal Rod System is intended for the treatment of DDD (degenerative disc disease defined as back pain of discogenic origin with degeneration of the disc confirmed by history or radiographic studies), pseudoarthrosis, stenosis, deformities (scoliosis, kyphosis, lordosis), spondylolisthesis, fracture, previous failed fusion, or tumor resection. The Thoracolumbar Spinal Rod System is limited to non-cervical use.

Thoracolumbar Spinal System

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Summary of Safety and Effectiveness

INTENDED USE:

***Pedicle Screw Fixation***

(continued)

When used as a pedicle screw system, in the spine of skeletally mature patients, the Thoracolumbar Spinal Rod System is indicated for patients: (a) having severe spondylolisthesis (Grades 3 and 4) at the L5-S1 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 (L3 and below); and (d) who are having the device removed after the development of a solid fusion mass.

In addition, when used as a pedicle screw system, in the non-cervical spine of skeletally mature patients, the Thoracolumbar Spinal Rod System is intended to provide immobilization and stabilization of spinal segments, as an adjunct to fusion, in the treatment of the following acute and chronic instabilities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

MATERIALS:

The material used is implant grade material that conforms to ASTM F138 standards for stainless steel.



DEC 22 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Sharon L. Murphy  
Regulatory Affairs Program Manager  
United States Surgical Corporation  
150 Glover Avenue  
Norwalk, Connecticut 06856

Re: K983899  
Trade Name: Thoracolumbar Spinal Rod System (Empower)  
K983904  
Trade Name: Rogozinski Spinal Rod System  
Regulatory Class: II  
Product Codes: MNI, MNH, KWQ, and KWP  
Dated: October 30, 1998  
Received: November 3, 1998

Dear Ms. Murphy:

We have reviewed your Section 510(k) notifications of intent to market the devices referenced above and we have determined these devices are substantially equivalent (for the indications for use stated in the enclosures) 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 devices, 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 devices are classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), they may be subject to such additional controls. Existing major regulations affecting your devices 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 devices in the Federal Register. Please note: this response to your pre-market notification submission does

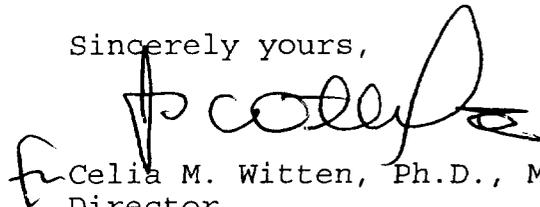
Page 2 - Ms. Sharon L. Murphy

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.

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

If you desire specific advice for your devices 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 devices, 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

Enclosures

Thoracolumbar Spinal System

Indications for Use

510(k) Number (if known): K983899

Device Name: Thoracolumbar Spinal Rod System

Indications For Use:

**Non-Pedicle Screw Fixation**

When used as an anterior spinal system the Thoracolumbar Spinal Rod System is intended for the treatment of DDD (degenerative disc disease defined as back pain of discogenic origin with degeneration of the disc confirmed by history or radiographic studies), pseudoarthrosis, stenosis, deformities (scoliosis, kyphosis, lordosis), spondylolisthesis, fracture, previous failed fusion, or tumor resection. The Thoracolumbar Spinal Rod System is limited to non-cervical use.

When used as a posterior, non-pedicle spinal system (consisting of hooks and sacral/ilic screws), the Thoracolumbar Spinal Rod System is intended for the treatment of DDD (degenerative disc disease defined as back pain of discogenic origin with degeneration of the disc confirmed by history or radiographic studies), pseudoarthrosis, stenosis, deformities (scoliosis, kyphosis, lordosis), spondylolisthesis, fracture, previous failed fusion, or tumor resection. The Thoracolumbar Spinal Rod System is limited to non-cervical use.

**Pedicle Screw Fixation**

When used as a pedicle screw system, in the spine of skeletally mature patients, the Thoracolumbar Spinal Rod System is indicated for patients: (a) having severe spondylolisthesis (Grades 3 and 4) at the L5-S1 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 (L3 and below); and (d) who are having the device removed after the development of a solid fusion mass.

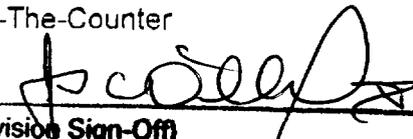
In addition, when used as a pedicle screw system, in the non-cervical spine of skeletally mature patients, the Thoracolumbar Spinal Rod System is intended to provide immobilization and stabilization of spinal segments, as an adjunct to fusion, in the treatment of the following acute and chronic instabilities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: X OR Over-The-Counter

Use: \_\_\_\_\_  
(Per 21 CFR 801.109)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K983899