

K974213

IX. Summary of Safety and Effectiveness

SUBMITTER: United States Surgical Corporation
150 Glover Avenue
Norwalk, CT 06856

FEB - 4 1998

CONTACT PERSON: Sharon L. Murphy

DATE PREPARED: November 7, 1997

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

COMMON NAME: Titanium Spinal Rod System

PROPRIETARY NAME: Aurora Titanium Spinal Rod System

PREDICATE DEVICES:

- ◆ USSC's (formerly Smith & Nephew's) Aurora Titanium Spinal Rod System (K970635)
- ◆ USSC's (formerly Smith & Nephew's) Rogozinski Spinal Rod System
- ◆ Smith & Nephew's Richard's Titanium Plating System
- ◆ Sofamor Danek's Danek TSRH Spinal System
- ◆ Depuy Moss® Miami System

INTENDED USE: The components of the Titanium Spinal Rod System are indicated for spinal fixation. When used as an anterolateral/anterior system consisting of rods and screws, the levels of attachment are the lumbar, thoracic and cervical spine. The points of attachment and methods are screw fixation to the anterolateral vertebral bodies of the lumbar and thoracic spine(T6-L5) and the anterior vertebral bodies of the cervical spine. The indications are degenerative disc disease defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies, spondylolisthesis, fracture, spinal stenosis, deformities (i.e., scoliosis, kyphosis, lordosis), tumor, pseudoarthrosis, multi-operated back or revision of previous surgery.

When used as a nonpedicle posterior system consisting of hooks, crosslinks and sacral/iliac screws the levels of attachment are the lumbar, thoracic and cervical spine and the sacrum and ilium. Intended uses include hook and sacral screw fixation to the lumbar spine, noncervical spine and to the T1-S1 spine; and hook and sacral/iliac screw fixation to the noncervical spine. The indications are degenerative disc disease defined as back pain of

discogenic origin with degeneration of the disc confirmed by history and radiographic studies, spondylolisthesis, fracture, spinal stenosis, deformities (i.e. scoliosis, kyphosis, lordosis), tumors, pseudoarthrosis, multi-operated back or revision of previous surgery.

When used as a posterior pedicle system consisting of hooks, crosslinks, sacral/iliac screws, pedicle screws and connectors the levels of attachment are lumbar, thoracic and cervical spine and the sacrum and ilium. The device system using pedicle screws is intended 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; and (d) who are having the device removed after the development of a solid fusion mass. Although the levels of fusion may not go above the L5-S1 joint, the levels of pedicle screw fixation may be L3-S1.

These device components are for single use. Cementless or cement fixation is not applicable to these components.

MATERIALS:

The material used is implant grade material that conforms to ASTM F136 and ISO 5835/3 standards for wrought Titanium alloy (Ti-6Al-4V).



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 4 1998

Ms. Sharon L. Murphy
• Senior Regulatory Affairs Associate
United States Surgical Corporation
150 Glover Avenue
Norwalk, Connecticut 06856

Re: K974213
Aurora Titanium Spinal Rod System Components
(Aurora Titanium Spinal Rod System)
Regulatory Class: II
Product Codes: MNH, KWQ, and KWP
Dated: November 7, 1997
Received: November 10, 1997

Dear Ms. Murphy:

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.

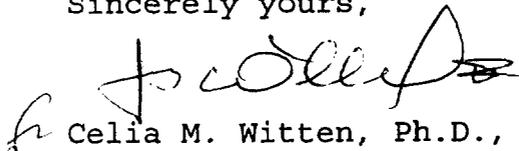
FDA advises that the use of your device system with any other device components but those identified in this 510(k) would require submission of a new 510(k) providing documentation of design, material, and labeling compatibility between the device components. Mechanical testing of a spinal system

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,



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

IV. Indications for Use

510(k) Number (if known): K974213

Device Name: Aurora Titanium Spinal Rod System Components

Indications For Use:

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When used as an anterolateral/anterior system consisting of rods and screws, the levels of attachment are the lumbar, thoracic and cervical spine. The points of attachment and methods are screw fixation to the anterolateral vertebral bodies of the lumbar and thoracic spine(T6-L5) and the anterior vertebral bodies of the cervical spine. The indications are degenerative disc disease defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies, spondylolisthesis, fracture, spinal stenosis, deformities (i.e., scoliosis, kyphosis, lordosis), tumor, pseudoarthrosis, multi-operated back or revision of previous surgery.

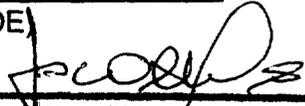
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: OR Over-The-Counter Use: _____
(Per 21 CFR 801.109)



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K974213