K982990

OCT 21 1998

TSRH® Spinal System
510(k) Summary
K982990
October 1998

I. **Company:** Sofamor Danek USA
1800 Pyramid Place
Memphis, TN 38132
(901) 396-3133

II. **Proposed Proprietary Trade Name:** TSRH® Spinal System

III. **Description**

The purpose of this 510(k) notification is to expand the indications of use of the system and to add components to the system.

The TSRH® Spinal System consists of a variety of shapes and sizes of rods, hooks, screws, cross connectors, and connecting components. In addition, GDLH® rods, DYNA-LOK® bolts, CD HORIZON™ Low Profile MULTI-SPAN™ CROSSLINK® Plates, GDLH® rod/bolt connectors, GDLH® Variable Angle T-Bolts, and GDLH® and CD HORIZON™ set screws and locking screws may be used with the TSRH® Spinal System.

The TSRH® Spinal System implant components can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case. The hooks are intended for posterior use only and the staples are for anterior use only. All CROSSLINK® Plates are for posterior use and the CROSSLINK Axial and Offset Plates may be used anteriorly as well.

The TSRH Spinal System components are fabricated from either ASTM F-138 stainless steel or F-136 titanium alloy (or their ISO equivalents) and may be sold sterile or non-sterile.

IV. **Indications for Use**

When used as a pedicle screw fixation system of the non-cervical posterior spine in skeletally mature patients, the TSRH® Spinal System is indicated for one or more of the following: (1) degenerative spondylolisthesis with objective evidence of neurologic impairment, (2) fracture, (3) dislocation, (4) scoliosis, (5) kyphosis, (6) spinal tumor, and/or (7) failed previous fusion (pseudarthrosis).

In addition, when used as a pedicle screw fixation system, the TSRH® Spinal System is indicated for skeletally mature 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 (L3 and below); and (4) who are having the device removed after the development of a solid fusion mass.

When used as a posterior, non-cervical, non-pedicle screw fixation system, the TSRH® Spinal System is intended for the following indications: (1) degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), (2) spinal stenosis, (3) spondylolisthesis, (4) spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis), (5) fracture, (6) pseudarthrosis, (7) tumor resection, and/or (8) failed previous fusion.

When used as an anterolateral thoracic/lumbar system, the TSRH® Spinal System is intended for the following indications: (1) degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), (2) spinal stenosis, (3) spondylolisthesis, (4) spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis), (5) fracture, (6) pseudarthrosis, (7) tumor resection, and/or (8) failed previous fusion.

V. The TSRH Spinal System was declared substantially equivalent to itself. The new pedicle screw classification indications described in the classification Final Rule published in the July 27,1998 Federal Register were referenced. Mechanical test data, engineering drawings, sterilization validation, and other data were referenced in other Sofamor Danek 510(k) applications or provided in the application.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 21 1998

Richard W. Treharne, Ph.D.
Vice President
Research and Regulatory Affairs
Sofamor Danek
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K982990
TSRH® Spinal System - additional components
Regulatory Class: II
Product Codes: MNI, KWP, KWQ, and MNH
Dated: August 25, 1998
Received: August 26, 1998

Dear Dr. Treharne:

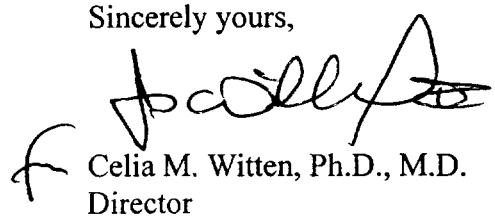
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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 (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 requirements, 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.

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" (21CFR 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/dsma/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

October, 1998

510(k) Number (if known): K982990

Device Name: TSRH® Spinal System

Indications for Use:

When used as a pedicle screw fixation system of the non-cervical posterior spine in skeletally mature patients, the TSRH® Spinal System is indicated for one or more of the following: (1) degenerative spondylolisthesis with objective evidence of neurologic impairment, (2) fracture, (3) dislocation, (4) scoliosis. (5) kyphosis, (6) spinal tumor, and/or (7) failed previous fusion (pseudarthrosis).

In addition, when used as a pedicle screw fixation system, the TSRH® Spinal System is indicated for skeletally mature 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 (L3 and below); and (4) who are having the device removed after the development of a solid fusion mass.

When used as a posterior, non-cervical, non-pedicle screw fixation system, the TSRH® Spinal System is intended for the following indications: (1) degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), (2) spinal stenosis, (3) spondylolisthesis, (4) spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis), (5) fracture, (6) pseudarthrosis, (7) tumor resection, and/or (8) failed previous fusion.

When used as an anterolateral thoracic/lumbar system, the TSRH® Spinal System is intended for the following indications: (1) degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), (2) spinal stenosis, (3) spondylolisthesis, (4) spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis), (5) fracture, (6) pseudarthrosis, (7) tumor resection, and/or (8) failed previous fusion.

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

Concurrence of CDRH, Office of Evaluation (ODE)

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

(Optional 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K982990