

OCT 5 1998

TENOR™ Spinal System
510(k) Summary
K982490

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

II. Proposed Proprietary Trade Name: TENOR™ Spinal System

III. Product Description

The TENOR™ Spinal System is a spinal device intended to provide temporary, bilateral stabilization and augment the development of a solid spinal fusion. The system comprises a variety of shapes and sizes of clamps, cross connectors, nuts, and screws made of medical grade titanium alloy. The TENOR™ Spinal System is used in conjunction with GDLH™ 5.5mm titanium alloy rods. Additionally, the TENOR™ Spinal System may be used with titanium alloy TSRH® hooks, TSRH® Low Profile CROSSLINK® plates, and MULTI AXIAL Low Profile MULTI-SPAN™ CROSSLINK® plates for attachment to the posterior thoracic and lumbar spine. These components are assembled to fit the patient's specific anatomic needs.

IV. Indications

The TENOR™ Spinal System, when used for pedicle screw fixation, 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 (levels of pedicle screw fixation may be from L3 to sacrum); and (d) who are having the device removed after the development of a solid fusion mass.

The TENOR™ Spinal System, when used as a non-pedicle screw fixation 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.) Pseudarthrosis, 3.) Stenosis, 4.) Spondylolisthesis, 5.) Spinal deformities: scoliosis, kyphosis, lordosis, 6.) Fracture, 7.) Unsuccessful previous attempts at spinal fusion, 8.) Tumor resection.

V. Substantial Equivalence

The TENOR™ Spinal System is substantially equivalent to the CD™ Horizon, TSRH®, and DYNA-LOK® Spinal Systems manufactured by Sofamor Danek. Mechanical testing and other information were provided to demonstrate substantial equivalence.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 5 1998

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

Re: K982490
TENOR™ Spinal System
Regulatory Class: II
Product Codes: MNH and KWP
Dated: July 13, 1998
Received: July 17, 1998

Dear Dr. Treharne:

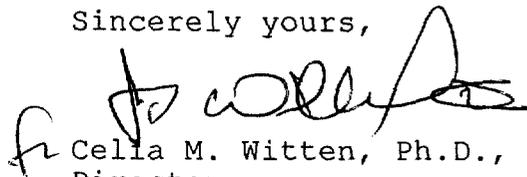
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 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.

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

510(k) Number (if known): K982490

Device Name: TENOR™ Spinal System

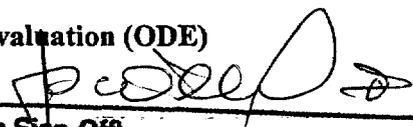
Indications for Use:

The TENOR™ Spinal System, when used for pedicle screw fixation, 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 (levels of pedicle screw fixation may be from L3 to sacrum); and (d) who are having the device removed after the development of a solid fusion mass.

The TENOR™ Spinal System, when used as a posterior, non-pedicle screw fixation 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. Pseudarthrosis; 3. Stenosis; 4. Spondylolisthesis; 5. Spinal deformities: scoliosis, kyphosis, lordosis; 6. Fracture; 7. Unsuccessful previous attempts at spinal fusion; 8. Tumor resection.

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Concurrence of CDRH, Office of Evaluation (ODE)



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K982490

Prescription Use X
(Per 21 CFR 801.109)
(Optional 1-2-96)

OR

Over-the-counter Use _____