

MAY 19 1999

**TENOR™ Spinal System – K991364****510(k) Summary****May 13<sup>th</sup>, 1999**

**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, washers, plates, and screws made of medical grade titanium alloy or stainless steel. The TENOR™ Spinal System may be used in conjunction with GDLH™ 5.5mm rods, TSRH® hooks and connectors, TSRH® Low Profile CROSSLINK® plates, CD HORIZON™ Low Profile MULTI-SPAN™ CROSSLINK® plates, and/or 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.

TENOR™ Plates are intended for the L5-S1 pedicle screw indication described above only.

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. When used for posterior non-pedicle screw fixation, the TENOR™ Spinal System is intended for thoracic, lumbar, and sacral (T1 – Sacrum) fixation only.

**V. Substantial Equivalence**

Documentation was provided which demonstrated the TENOR™ Spinal System to be substantially equivalent to itself.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAY 19 1999

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

Re: K991364  
Trade Name: TENOR™ Spinal System  
K991460  
Trade Name: ZPlate-ATL™ Anterior Fixation System  
Regulatory Class: II  
Product Codes: MNH and KWP  
Dated: April 19 and 26, 1999  
Received: April 20 and 27, 1999

Dear Dr. Treharne:

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.

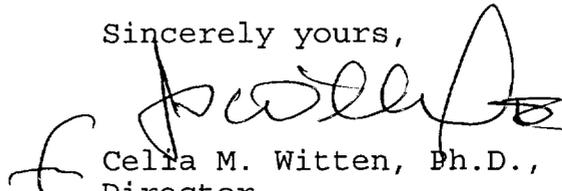
If your devices are classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), they may be subject to such additional controls. Existing major regulations affecting your devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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

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,



Cella M. Witten, Ph.D., M.D.  
Director  
Division of General and  
Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosures

510(k) Number (if known): K991364

Device Name: TENOR™ Spinal System

Indications for Use:

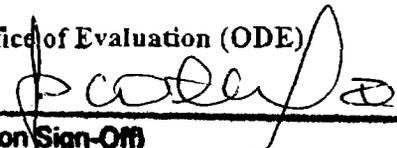
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Concurrence of CDRH, Office of Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K991364

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

OR

Over-the-counter Use \_\_\_\_\_