MAY 28 1999

TENOR™ Spinal System – K991528
510(k) Summary
May 20th, 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, connectors, 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 28 1999

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

Re: K991528
Trade Name: TENOR™ Spinal System
Regulatory Class: II
Product Codes: MNH and KWP
Dated: April 30, 1999
Received: May 3, 1999

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 at (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): K991528

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.

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.

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

Concurrence of CDRH, Office of Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K991528

Prescription Use X OR Over-the-counter Use _____
(Per 21 CFR 801.109)
(Optional 1-2-96)