

MAY 19 1999

**Z-PLATE ATL™ Anterior Spinal Fixation System**  
**510(k) Summary**  
**April 26, 1999**

K 99 1460

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

**II. Proprietary Trade Name: ZPLATE-ATL™ Anterior Spinal Fixation System**

**III. Product Description**

The ZPLATE-ATL™ Anterior Spinal Fixation System consists of a variety of shapes and sizes of plates, bolts, screws, washers and nuts, as well as ancillary products and instrument sets. The components can be locked into a variety of configurations, with each construct tailor-made for the individual case.

**IV. Indications**

The ZPLATE-ATL™ Anterior Fixation System is intended for screw/bolt fixation/attachment to the anterolateral intervertebral bodies from T1 to L5 only. This system is to be used only on one side and placed in such a manner as to be as far away from blood vessels such as the aorta and nerve roots as possible.

When properly used, this system will provide temporary stabilization until a solid spinal fusion develops. Specific indications include:

1. Degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies).
2. Pseudoarthrosis.
3. Spondylolysis.
4. Spondylolisthesis.
5. Fracture.
6. Neoplastic disease.
7. Unsuccessful previous fusion surgery.
8. Lordotic deformities of the spine.
9. Idiopathic thoracolumbar or lumbar scoliosis
10. Deformity (i.e., scoliosis, lordosis, and/or kyphosis) associated with deficient posterior elements such as that resulting from laminectomy, spina bifida, or myelomenigocele.
11. Neuromuscular deformity (i.e., scoliosis, lordosis, and / or kyphosis) associated with pelvic obliquity.

**Warning: This device is not approved for screw attachment to the posterior elements (pedicle) of the cervical, thoracic, or lumbar spine.**

**V. Substantial Equivalence**

Documentation was provided which demonstrated the ZPLATE-ATL™ Anterior Spinal Fixation 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 (Premarket 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 premarket notification submission does

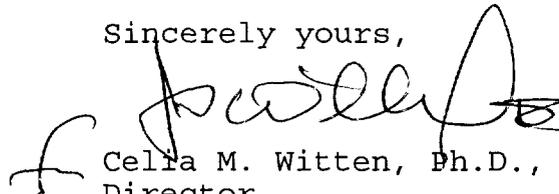
Page 2 - Richard W. Treharne, Ph.D.

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): \_\_\_\_\_

Device Name: ZPLATE-ATL™ Anterior Fixation System

**Indications for Use:**

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| 5. Fracture.   |  |
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| 7. Unsuccessful previous fusion surgery.   |  |
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(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

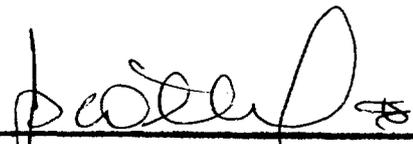
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**Concurrence of CDRH, Office of Evaluation (ODE)**

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

OR

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

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number 12991460