

MAR 10 1999

K990603

Z-PLATE ATL™ Anterior Spinal Fixation System
510(k) Summary
February 22, 1999

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 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). | 9. Idiopathic thoracolumbar or lumbar scoliosis |
| 2. Pseudoarthrosis. | 10. Deformity (i.e., scoliosis, lordosis, and/or kyphosis) associated with deficient posterior elements such as that resulting from laminectomy, spina bifida, or myelomeningocele. |
| 3. Spondylolysis. | 11. Neuromuscular deformity (i.e., scoliosis, lordosis, and / or kyphosis) associated with pelvic obliquity. |
| 4. Spondylolisthesis. | |
| 5. Fracture. | |
| 6. Neoplastic disease. | |
| 7. Unsuccessful previous fusion surgery. | |
| 8. Lordotic deformities of the spine. | |

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.



MAR 10 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K990603
Trade Name: ZPLATE-ATL™ Anterior Fixation System
Regulatory Class: II
Product Code: KWQ
Dated: February 22, 1999
Received: February 23, 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.

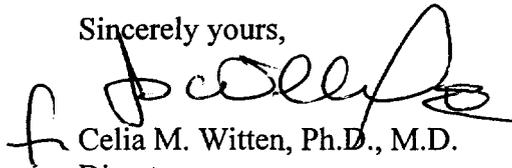
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

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

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,

A handwritten signature in black ink, appearing to read 'C. Witten', is written over the typed name.

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): K990603

Device Name: ZPLATE-ATL™ Anterior Fixation System

Indications for Use:

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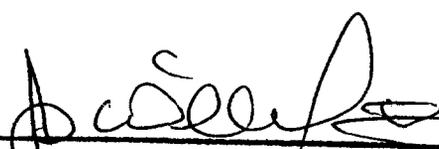
(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

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 K990603