

NOV 12 1998

**TOWNLEY Pedicle Screw Plating System
510(k) Summary
November 4th, 1998**

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

II. Proprietary Trade Name: TOWNLEY Pedicle Screw Plating System

III. Product Description

This system consists of a broad-headed, partially threaded screw designed to compress bone grafts. Screw lengths range from 0.5 to 2.5 inches. Both cortical and cancellous screw threads are available. The screw comes in two configurations: flat-head or hex. The hex screws are wider in diameter. The DYNA-LOK® plates are used to interconnect two or more vertebrae together via screw fixation through the pedicles. The components are made of titanium alloy such as described by ASTM F-136 or ISO 5832-3. Alternatively, the entire system may be made out of medical grade stainless steel such as described by ASTM F-138 or ISO 5832-1 or ISO 5832-9. This 510(k) submission seeks to add the titanium alloy components to the TOWNLEY Pedicle Screw Plating System.

IV. Indications

The TOWNLEY Pedicle Screw Plating System is intended to stabilize the spine as an aid to fusion. After first making drill holes in the pedicles, a DYNA-LOK® Plate is positioned over the pedicles. TOWNLEY Pedicle screws are then inserted through the plate, down the center of the pedicles, and into the vertebral body. Bone graft must be used with each procedure.

This system is indicated for the treatment of any or all of the following at the C2 to S1 (inclusive) spinal levels: (a) Trauma, including spinal fractures and/or dislocations, (b) Spondylolisthesis, all grades and types, (c) Spondylolysis, (d) Pseudarthrosis, (e) Degenerative disc disease and/or degenerative diseases which include: (1) degenerative disc disease (ddd) as defined by neck and/or back pain of discogenic origin as confirmed by patient history with degeneration of the disc as confirmed by radiographic studies and/or (2) degenerative disease of the facets with instability.

For all these indications, bone graft must be used and the system is limited to screw fixation from C2 to S1.

V. Substantial Equivalence

Documentation was provided which demonstrated the TOWNLEY Pedicle Screw Plating System to be substantially equivalent to itself.



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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: K983706
Townley Pedicle Screw Plating System
Regulatory Class: II
Product Codes: MNI, MNH, and KWP
Dated: October 20, 1998
Received: October 21, 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.

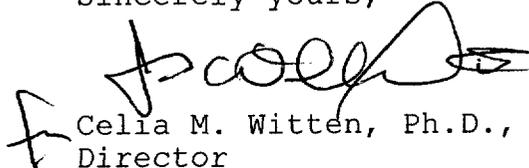
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

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 (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): K983706

Device Name: TOWNLEY Pedicle Screw Plating System

Indications for Use:

The TOWNLEY Pedicle Screw Plating System is intended to stabilize the spine as an aid to fusion. After first making drill holes in the pedicles, a DYNA-LOK® Plate is positioned over the pedicles. TOWNLEY Pedicle screws are then inserted through the plate, down the center of the pedicles, and into the vertebral body. Bone graft must be used with each procedure.

This system is indicated for the treatment of any or all of the following at the C2 to S1 (inclusive) spinal levels: (a) Trauma, including spinal fractures and/or dislocations, (b) Spondylolisthesis, all grades and types, (c) Spondylolysis, (d) Pseudarthrosis, (e) Degenerative disc disease and/or degenerative diseases which include: (1) degenerative disc disease (ddd) as defined by neck and/or back pain of discogenic origin as confirmed by patient history with degeneration of the disc as confirmed by radiographic studies and/or (2) degenerative disease of the facets with instability.

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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 _____

K983706
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