K013829

DEC 1 9 2001

TOWNLEY™ Transfacetpedicular Screw Fixation System
510(k) Summary
November 2001

I. **Company:**

Medtronic Sofamor Danek USA, Inc.
1800 Pyramid Place
Memphis, TN 38132
(901) 396-3133

II. **Proprietary Trade Name:** TOWNLEY™ Transfacetpedicular Screw Fixation System

III. **Product Description:** The TOWNLEY™ Transfacetpedicular Screw Fixation System consists of screws designed to compress bone grafts. The screws are fabricated from medical grade stainless steel described by such standards as ASTM F-138 or ISO 5832-1 or ISO 5832-9, or titanium alloy conforming to such standards as ASTM F-136 or ISO 5832-3. The screws may be used with or without DYNALOK plates. DYNALOK plates are used as spinous process plates to connect two or more screws together on one side of the spine at the base of the spinous process when the system is used for the second fixation method described below. Stainless steel and titanium implant components should never be used in the same construct. The purpose of this submission is to add a 4.0mm titanium cortical bone screw to the system.

IV. **Indications:** The TOWNLEY™ Transfacetpedicular Screw Fixation System is intended to stabilize the spine as an aid to fusion by two different fixation methods. The first fixation method uses the Transfacetpedicular Screws as just facet fixation screws, where the screws are inserted bilaterally through the superior side of the facet, across the facet joint at (usually) a single level, and into the pedicle.

In the second fixation method, the TOWNLEY™ Transfacetpedicular Screws are inserted bilaterally through the superior side of the facet, across the facet joint, and into the pedicle at multiple levels at the same time that a DYNALOK® Plate is attached to the base of the spinous processes at the corresponding levels with Transfacetpedicular Screws. The second fixation method should be used when the spine has increased instability or multiple levels need to be fused. Bone graft must be used for both fixation methods.

For both methods, this system is indicated for the posterior surgical treatment of any or all of the following at the C2 to S1 (inclusive) spinal levels: 1) rauma, including spinal fractures and/or dislocations; 2) Spondylolisthesis; 3) Spondylolysis; 4) Pseudarthrosis or failed previous fusions which are symptomatic or which may cause secondary instability or deformity; 5) Degenerative diseases which include: (a) 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 (b) degenerative disease of the facets with instability.

V. **Substantial Equivalence:** Documentation was provided which demonstrated the TOWNLEY™ Transfacetpedicular Screw Fixation 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

DEC 1 9 2001

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

Re: K013829
Trade/Device Name: TOWNLEY™ Transfacetpedicular Fixation System
Product Code: MRW
Dated: November 16, 2001
Received: November 19, 2001

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, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

November 2001

510(k) Number (if known): K013829

Device Name: TOWNLEY™ Transfacetpedicular Screw Fixation System

Indications for Use:

The TOWNLEY™ Transfacetpedicular Screw Fixation System is intended to stabilize the spine as an aid to fusion by two different fixation methods. The first fixation method uses the TOWNLEY™ Transfacetpedicular Screws as just facet fixation screws, where the screws are inserted bilaterally through the superior side of the facet, across the facet joint at (usually) a single level, and into the pedicle.

In the second fixation method, the TOWNLEY™ Transfacetpedicular Screws are inserted bilaterally through the superior side of the facet, across the facet joint, and into the pedicle at multiple levels at the same time that a DYNALOK® Plate is attached to the base of the spinous processes at the corresponding levels with Transfacetpedicular Screws. The second fixation method should be used when the spine has increased instability or multiple levels need to be fused. Bone graft must be used for both fixation methods.

For both methods, this system is indicated for the posterior surgical treatment of any or all of the following at the C2 to S1 (inclusive) spinal levels: 1) Trauma, including spinal fractures and/or; dislocations; 2) Spondylolisthesis; 3) Spondylolysis; 4) Pseudarthrosis or failed previous fusions which are symptomatic or which may cause secondary instability or deformity; 5) Degenerative diseases which include: (a) 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 (b) degenerative disease of the facets with instability.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013829

000026