K091883

SEP 21 2009

T2™ Spinal System
510(k) Summary
June 2009

I. **Company:**

Medtronic Sofamor Danek, Inc.
1800 Pyramid Place
Memphis, Tennessee 38132
Telephone: (901) 396-3133
Fax: (901) 346-9738

Contact: Theresa Leister
Sr. Regulatory Affairs Specialist

II. **Product Name:** T2™ Spinal System
Classification: MQP

III. **Description:** The T2™ Spinal System is a distractible system used in corpectomy procedures. This construct is inserted between two vertebral bodies in the thoracic and/or lumbar spine and is expanded to aid in the surgical correction and stabilization of the spine. The construct is not intended to be used as a stand alone device. The construct is intended to be used with either anterior and/or posterior supplemental spinal fixation systems already cleared for thoracic and lumbar spine stabilization.

The T2 ™ Spinal System contains an expandable centerpiece, which is made of titanium alloy, cobalt chrome, and nitinol and is available in multiple diameters and heights to accommodate the patient's anatomical requirements. The T2™ Spinal System's end caps are attached to the T2™ Spinal System's expandable centerpieces to accommodate the individual anatomical requirements of the vertebral space created by the corpectomy.

T2™ Spinal System constructs may not be used with stainless steel supplemental fixation devices. Titanium constructs comprised from one of the following Medtronic spinal systems or their successors must be used with the T2™ Spinal System.

	Anterior	Posterior
ZPLATE-II™ Anterior Fixation System	√	
DYNALOK CLASSIC® Spinal System	√	√
VANTAGE® Anterior Fixation System	√	
TSRH® Spinal System	√	√
CD HORIZON® Spinal System	√	√

IV. **Indications for Use:** The T2™ Spinal System is a vertebral body replacement system intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture). The T2™ components consist of end caps which must be attached to a T2 XVBR™ expanding centerpiece to form a complete construct. The final construct is to be used with supplemental fixation. The T2 SCEPTOR™ components also serve as a vertebral body replacement device for the same intended use in the thoracolumbar spine. The T2 SCEPTOR™ end caps and endcleats must be attached to a PYRAMESH-C® device to form a complete construct. Both constructs (T2 XVBR™ and T2 SCEPTOR™) must be used with supplemental fixation to form a final construct. Specifically, the construct is to be used with the Medtronic ZPLATE II™ Anterior Fixation System, the DYNALOK CLASSIC® Spinal System, the VANTAGE™ Anterior Fixation System, the TSRH® Spinal System, the CD HORIZON® Spinal System, or their successors. Additionally, the T2™ Spinal System construct is intended to be used with allograft and/or autograft.

V. **Substantial Equivalence:** Documentation was provided which demonstrated that the T2™ Spinal System components are substantially equivalent to previously cleared devices such as the T2 XVBR™ Spinal System K082112 (SE 08/27/2008) and the T2 SCEPTOR™ Spinal System K063491 (SE 3/5/2007).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

SEP 21 2009

Medtronic Sofamor Danek USA, Inc.
% Ms. Theresa Leister
Senior Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K091883
Trade/Device Name: T2™ Spinal System
Regulation Number: 21CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: MQP
Dated: June 23, 2009
Received: June 24, 2009

Dear Ms. Leister:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K091883

Device Name: T2™ Spinal System

Indications for Use:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use __X__ OR Over-The-Counter Use _____
Per 21 CFR 801.109

Karen L. Burns for MXM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091883