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K071033

MEDTRONIC Sofamor Danek
T2™ Spinal System 510(k) Summary
April 2007

AUG 14 2007

I. **Company:** Medtronic Sofamor Danek, Inc.
1800 Pyramid Place
Memphis, Tennessee 38132
(901) 396-3133

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, baskets, and covers 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 a series of end caps, baskets, and covers 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 bone graft.

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™ SCEPTOR™ Spinal System K063491 (SE 3/5/2007), the VERTE-STACK® Spinal System K052931 (SE 11/16/2005), the VERTE-SPAN™ Spinal System K024049 (SE 2/26/2003), the VENTURE™ Anterior Cervical Plate System K042922 (SE 11/19/2004), the CD HORIZON® Spinal System K992928 (SE 9/21/1999) and K043488 (SE 3/22/2005).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Metronic Sofamor Danek, Inc.
% Ms. Christine Scifert
Group Director, Regulatory Affairs
1800 Pyramid Place
Memphis, TN 38132

AUG 14 2007

Re: K071033
Trade/Device Name: T2™ Spinal System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: MQP
Dated: April 11, 2007
Received: April 12, 2007

Dear Mr. Dale Davison:

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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

CONFIDENTIAL

April 2007

510(k) Number (if known): _____

Device Name: T2™ Spinal System

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 a series of end caps, baskets, and covers 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 bone graft.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K071033