January 16, 2019

Medtronic Sofamor Danek, USA Inc.
Elizabeth Hamilton
Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K183510
Trade/Device Name: T2 STRATOSPHERE™ Expandable Corpectomy System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: MQP, PLR
Dated: December 13, 2018
Received: December 18, 2018

Dear Ms. Hamilton:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Melissa Hall -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K183510

Device Name

T2 Stratosphere™ Expandable Corpectomy System

Indications for Use *(Describe)*

Cervical and Thoracolumbar

The T2 Stratosphere™ Expandable Corpectomy System is a vertebral body replacement device intended for use in the thoracic and lumbar spine (T1-L5) and cervical spine (C2-C7). The T2 Stratosphere™ Expandable Corpectomy System is intended for use in skeletally mature patients.

When used in the cervical spine, the T2 Stratosphere™ Expandable Corpectomy System is used to replace a collapsed, damaged, or unstable vertebral body caused by tumor, trauma (i.e. fracture), or osteomyelitis, or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues in cervical degenerative disorders. When used in the cervical spine, the T2 Stratosphere™ Expandable Corpectomy System may not be used with optional modular end caps. When used in the cervical spine at single or two levels, the T2 Stratosphere™ Expandable Corpectomy System is intended to be used with supplemental fixation for use in the cervical spine. When used at more than two levels, supplemental fixation should include posterior fixation cleared for use in the cervical spine.

When used in the thoracic and lumbar spine, the T2 Stratosphere™ Expandable Corpectomy System is used to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e. fracture). The T2 Stratosphere™ Expandable Corpectomy centerpiece may be used with or without optional modular end caps which accommodate individual anatomic requirements. The device is to be used with supplemental fixation cleared for use in the thoracic and lumbar spine.

When used in the cervical spine, the T2 Stratosphere™ Expandable Corpectomy System is intended for use with autograft or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft as an adjunct to fusion. When used in the thoracic and lumbar spine, the T2 Stratosphere™ Expandable Corpectomy System is intended for use with autograft or allograft as an adjunct to fusion. The T2 Stratosphere™ Expandable Corpectomy System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time in patients with advanced stage tumors involving the cervical and/or thoracolumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion, with bone graft used at the surgeon's discretion.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K183510

Device Name

T2 Stratosphere™ Expandable Corpectomy System

Indications for Use *(Describe)*

Thoracolumbar

The T2 Stratosphere™ Expandable Corpectomy System is a vertebral body replacement device intended for use in the thoracic and lumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e. fracture). The T2 Stratosphere™ Expandable Centerpiece may be used with or without optional modular end caps which accommodate individual anatomic requirements. The device is to be used with supplemental fixation cleared for use in the thoracic and lumbar spine.

The T2 Stratosphere™ Expandable Corpectomy System is intended for use with autograft or allograft, as an adjunct to fusion. The T2 Stratosphere™ Expandable Corpectomy System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time in patients with advanced stage tumors involving the thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion, with bone graft used at the surgeon's discretion.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) SUMMARY

MEDTRONIC
T2 STRATOSPHERE™ Expandable Corpectomy System

December 2018

Submitter:	Medtronic Sofamor Danek, USA Inc. 1800 Pyramid Place Memphis, Tennessee 38132 Telephone: (901) 396-3133 Fax: (901) 346-9738
Contact Person	Elizabeth Hamilton Regulatory Affairs Specialist Direct Telephone: (901) 399-3395
Date Prepared	December 13, 2018
Name of Device	T2 STRATOSPHERE™ Expandable Corpectomy System
Common Name	Spinal Vertebral Body Replacement Device
Classification Name	Spinal Intervertebral Body Fixation Orthosis: 21 CFR 888.3060
Classification	Class II
Product Codes	MQP, PLR
Predicate Devices	There are three (3) Predicates: **Primary Predicate 1-** T2 Stratosphere™ Expandable Corpectomy System (K181328, S.E. 09/19/2018) **Predicate 2-** T2 Stratosphere™ Expandable Corpectomy System (K173125, S.E. 12/20/2017) **Predicate 3-**T2 XVBR™ System (K071033. S.E. 08/14/2007)
Description of Devices	The T2 STRATOSPHERE™ Expandable Corpectomy System is an adjustable vertebral body replacement device and features a self-adjusting end cap which provides continuous angulation between 0-8° in any direction to accommodate the patient's anatomical requirements. The T2 STRATOSPHERE™ Expandable Corpectomy may be used in the thoracolumbar and cervical spine. The T2 STRATOSPHERE™ Expandable Corpectomy devices for use in the cervical spine are restricted to 13mm

	diameter centerpieces. Only the 13mm devices are cleared for both cervical and thoracolumbar region of the spine. The device is inserted between two vertebral bodies in the thoracolumbar or cervical spine and is expanded to aid in the surgical correction and stabilization of the spine. The device may be implanted through a lateral, oblique, or posterior approach using a minimally invasive technique or implanted through a lateral, oblique, posterior, or anterior approach through a traditional open technique. The T2 STRATOSPHERE™ Expandable Corpectomy System is intended to be used with supplemental fixation cleared for use in the cervical and thoracolumbar spine. The device is not intended to be used as a stand-alone implant. The T2 STRATOSPHERE™ Expandable Corpectomy System is made of titanium alloy (TI6A14V) in accordance with ASTM F136 *Standard Specification for Wrought Titanium- Aluminium-4 Vanadium ELI Alloy for Surgical Implant Applications*. The centerpieces are available in multiple diameters and heights. The system also features modular end caps which are available in various angles and geometries.
Indications for Use	**TL Indications** The T2 STRATOSPHERE™ Expandable Corpectomy 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 STRATOSPHERE™ Expandable Centerpiece may be used with or without optional modular end caps which accommodate individual anatomic requirements. The device is to be used with supplemental fixation cleared for use in the thoracolumbar spine. T2 STRATOSPHERE™ Expandable Corpectomy System is intended for use with autograft or allograft, as an adjunct to fusion. The T2 STRATOSPHERE™ Expandable Corpectomy System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time in patients with advanced stage tumors involving the thoracolumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion, with bone graft used at surgeon's discretion. **Cervical Indications** The T2 STRATOSPHERE™ Expandable Corpectomy System is a vertebral body replacement system intended for use in the thoracolumbar spine (T1-L5) and cervical spine (C2-C7). The T2 STRATOSPHERE™ Expandable Corpectomy System is intended for use in skeletally mature patients.

	When used in the cervical spine, the T2 STRATOSPHERE® Expandable System is used to replace a collapsed, damaged, or unstable vertebral body caused by tumor, trauma (i.e. fracture), or osteomyelitis, or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues in cervical degenerative disorders. When used in the cervical spine, the T2 STRATOSPHERE™ Expandable Corpectomy System may not be used with optional modular end caps. When used in the cervical spine at one or two levels, the T2 STRATOSPHERE™ Expandable Corpectomy System is intended to be used with supplemental fixation for use in the cervical spine. When used at more than two levels, supplemental fixation should include posterior fixation cleared for use in the cervical spine. When used in the thoracolumbar spine, the T2 STRATOSPHERE® Expandable System is used to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e. fracture). The T2 STRATOSPHERE™ Expandable Corpectomy System may be used with or without optional modular end caps which accommodate individual anatomic requirements. The device is to be used with supplemental fixation cleared for use in the thoracolumbar spine. When used in the cervical spine, the T2 STRATOSPHERE™ Expandable Corpectomy System is intended for use with autograft or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft as an adjunct to fusion. When used in the thoracolumbar spine, the T2 STRATOSPHERE™ Expandable Corpectomy System is intended for use with autograft or allograft as an adjunct to fusion. The T2 STRATOSPHERE™ Expandable Corpectomy System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time in patients with advanced stage tumors involving the cervical and/or thoracolumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion, with bone graft used at the surgeon's discretion.
Comparison of Technological Characteristics with the Predicate Devices	<u>T2 STRATOSPHERE™ Expandable Corpectomy System Implants</u> The subject T2 STRATOSPHERE™ Expandable Corpectomy System Implants have identical: indications for use, intended use, material (Titanium Alloy Per ASTM F136), levels of attachment, fundamental scientific technology and similar design as the T2 STRATOSPHERE™ Expandable Corpectomy devices previously cleared by the FDA in K181328, S.E. 09/19/2018 and K173125, S.E. 12/20/2017. The subject devices are identical to the predicates cleared within the T2 STRATOSPHERE™ Expandable Corpectomy system in terms of material, intended use, level of attachment, size range, material and fundamental scientific technology. The subject devices are very similar in design to the predicate devices and the only technological difference between the subject and predicate T2 Stratosphere™ Expandable Corpectomy System implants is the subject T2 STRATOSPHERE™ devices are provided sterile

	while the predicate T2 STRATOSPHERE™ devices are provided non-sterile. Additionally, the subject T2 STRATOSPHERE™ Expandable Corpectomy System Implants are provided sterile and are identical to that of Predicate 3 cleared by the FDA in K071033. S.E. 08/14/2007. The sterilization method used for the subject devices is identical to the sterilization method used for Predicate 3T2 XVBR™ System (K071033. S.E. 08/14/2007).
Performance Data	The following information is provided in support of substantial equivalence. Biocompatibility The subject, T2 STRATOSPHERE™ Expandable Corpectomy System Implants are permanent implants(>30days) and will be classified as body contacting devices according to FDA's Draft Guidance for Industry and FDA Staff "Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within risk management process." The subject implants are manufactured from identical materials as the predicate devices (K181328, S.E. 08/19/2018 and K173125, S.E. 12/20/2017) in accordance with the following standards: • ASTM F136, Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI Alloy for Surgical Implant Applications The manufacturing processes performed on the subject implants are standard industry practices and are identical to the predicates 1 and 2. Mechanical Testing The subject implants are the same as the predicate implants in terms of material, sizes and intended use. Mechanical testing for the predicate implants were tested in accordance with the following standards: • ASTM F2077, Test Methods For Intervertebral Body Fusion Devices • ASTM Draft Standard F-04.25.02.02, Static Push-out Test Method for Intervertebral Body Fusion Devices Staff Therefore, non-clinical mechanical testing was not performed on the Subject sterile implants. Detailed Mechanical Testing information is provided in the Predicate 2 (K173125, S.E 12/20/2017) submission. The subject devices do not introduce a new worst case, hence Medtronic believes that testing conducted on the predicate implants satisfies testing requirements for the subject devices. The subject devices do not introduce a new worst case scenario and are substantially equivalent to the predicate devices.
Pyrogenicity	

	The bacterial endotoxin test, also known as Limulus amebocyte lysate (LAL) test, was performed utilizing worst case subject implants to verify that the subject implants meet the 20 endotoxin units (EU)/device pyrogen limit specification. Testing was successfully performed, and it was confirmed that the subject implants meet the 20 EU/device testing limit for general medical devices that are implanted as outlined in ANSI/AAMI ST72, Bacterial endotoxins – Test methods, routine monitoring, and alternatives to batch testing and USP <161>, Medical Devices - Bacterial Endotoxin and Pyrogen Tests.
Conclusion	Based on the test results and additional supporting information provided in this premarket notification, Medtronic believes the subject devices are substantially equivalent to the the legally marketed predicate devices: • **Primary Predicate 1**- T2 STRATOSPHERE™ Expandable Corpectomy System, (K181328 S.E. 08/19/2018) • **Predicate 2**- T2 STRATOSPHERE™ Expandable Corpectomy System, (K181328 S.E. 08/19/2018) • **Predicate 3**- T2™ XVBR Spinal System (K071033, S.E. 08/14/2007)