December 20, 2017

Medtronic Sofamor Danek
Ms. Kanesha Hines
Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K173125
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
Dated: September 28, 2017
Received: September 29, 2017

Dear Ms. Hines:

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. 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); 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.

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Ronald P. Jean -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)*
K173125

Device Name
T2 STRATOSPHERE™ Expandable Corpectomy System

Indications for Use *(Describe)*
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 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.

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510(k) SUMMARY

MEDTRONIC
T2 STRATOSPHERE™ Expandable Corpectomy System

December 2017

Submitter:	Medtronic Sofamor Danek 1800 Pyramid Place Memphis, Tennessee 38132 Telephone: (901)396-3133 Fax: (901) 346-9738
Contact Person	Kanesha Hines Regulatory Affairs Specialist Direct Telephone: (901)399-2670
Date Prepared	December 7, 2017
Name of Device	T2 STRATOSPHERE™ Expandable Corpectomy System
Common Name	Spinal intervertebral body fixation orthosis
Classification Name	Spinal intervertebral body fixation orthosis: 21 CFR 888.3060
Classification	Class II
Product Codes	MQP 21 CFR 888.3060
Predicate Devices	There are 4 Predicates. **Primary Predicate 1-** T2 ALTITUDE™ Expandable Corpectomy System (K100976, S.E. 10/21/2010) **Predicate 2-** Aesculap HydroLift VBR (K083186, S.E. 03/04/2010) **Predicate 3-** T2 XVBR™ Spinal System (K071033, S.E. 08/14/2007) **Predicate 4-** VERTE-STACK Spinal System® (K052931, S.E. 11/16/2005) *The predicates have not been subject to a design related recall.*
Description of Devices	The T2 STRATOSPHERE™ Expandable Corpectomy System consists of centerpieces, modular end caps, and associated instruments. The T2 STRATOSPHERE™ Expandable Corpectomy System is intended for vertebral body replacement to

	aid in the surgical correction and stabilization of the spine for tumor and trauma pathologies.
Indications for Use	*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 the surgeon's discretion.*
Comparison of Technological Characteristics with the Predicate Devices	<u>T2 STRATOSPHERE™ Expandable Corpectomy System Implants</u> The primary predicate is T2 ALTITUDE™ Expandable Corpectomy System (K100976, S.E. 10/21/2010). The subject and predicate implants have identical intended use and similar indications and materials as Primary Predicate 1 (K100976, S.E. 10/21/2010) and Predicate 2 K083186, S.E. 03/04/2010). The predicate and subject devices have identical function and similar scientific fundamental technology. <u>T2 STRATOSPHERE™ Expandable Corpectomy System Instruments</u> The primary predicate is T2 ALTITUDE™ Expandable Corpectomy System (K100976, S.E. 10/21/2010). The predicate and subject devices have identical function and similar scientific fundamental technology.
Performance Data	<u>Mechanical Testing</u> In accordance with the Guidance for Industry and FDA Staff - Spinal System 510(k)'s,Medtronic has evaluated the subject devices to demonstrate substantial equivalence to the predicate devices. Design verification testing for the subject implants was completed in accordance with

	- 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 The tests completed were: - Static Compression - Compression Fatigue - Static Torsion - Torsion Fatigue - Expulsion The subject devices met the pre-determined acceptance criteria for all tests. Therefore, Medtronic believes design verification testing demonstrated that the subject implants are substantially equivalent to the predicate Medtronic devices. <u>MRI Testing</u> In accordance with the Guidance for Industry and FDA Staff – Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment, Medtronic has evaluated the subject devices to demonstrate substantial equivalence to the predicate devices. Medtronic believes that the subject implants do not present a new worst case and thus, can justifiably be classified as MR-Conditional.
Conclusion	Based on the test results and additional supporting information provided in this premarket notification, Medtronic believes the subject devices are at least as safe as and effective as the legally marketed predicate devices: • **Primary Predicate 1-** T2 ALTITUDE™ Expandable Corpectomy System (K100976, S.E. 10/21/2010) • **Predicate 2-** Aesculap HydroLift VBR (K083186, S.E. 03/04/2010) • **Predicate 3-** T2 XVBR™ Spinal System (K071033, S.E. 08/14/2007) • **Predicate 4-** VERTE-STACK Spinal System® (K052931, S.E. 11/16/2005)