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. 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...
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,

Brent Showalter -S

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

Enclosure
Indications for Use

510(k) Number (if known)
K181328

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) 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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

"DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW."

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”
510(k) SUMMARY

MEDTRONIC
T2 STRATOSPHERE™ Expandable Corpectomy System

September 2018

| Submitter: | Medtronic Sofamor Danek, USA Inc.  
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 | September 19, 2018 |
| Name of Device | T2 STRATOSPHERE™ Expandable Corpectomy System |
| Common Name | Spinal Vertebral Body Replacement Device |
| Classification | Class II |
| Product Codes | MQP, PLR 21 CFR 888.3060 |

Predicate Devices
There are six (6) Predicates.

**Primary Predicate 1** - Globus FORTIFY CORPECTOMY SPACERS (K162315, S.E. 11/09/2017)

**Predicate 2** - Aesculap MODULIFT VBR SYSTEM (K172032, S.E. 11/20/2017)

**Predicate 3** - Nuvasive X-CORE MINI CERVICAL EXPANDABLE VBR System (K151651, S.E. 09/25/2015)

**Predicate 4** - Osteotech VBR (K012254, S.E. 10/16/2001)

**Predicate 5** - Medtronic T2 ALTITUDE™ EXPANDABLE CORPECTOMY System (K100976, S.E. 10/21/2010)

**Predicate 6** - Medtronic T2 STRATOSPHERE™ EXPANDABLE CORPECTOMY System (K173125, S.E. 12/20/2017)

*The predicates have not been subject to a design related recall.*
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 devices for use in the cervical spine are restricted to 13mm diameter centerpieces. The T2 STRATOSPHERE™ Expandable Corpectomy System is made of titanium alloy. This 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 centerpieces are available in multiple heights.

The system also features modular end caps which are available in various angles and diameters that are only for use in the thoracolumbar spine.

The device is not intended to be used as a stand-alone implant.

Indications for Use

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 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 at one or two levels, the T2 STRATOSPHERE™ Expandable Corpectomy System may not be used with optional modular end caps. When used in the cervical spine 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.

<table>
<thead>
<tr>
<th>Comparison of Technological Characteristics with the Predicate Devices</th>
<th>T2 STRATOSPHERE™ Expandable Corpectomy System Implants</th>
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<tbody>
<tr>
<td>The primary predicate is Globus FORTIFY CORPECTOMY SPACERS (K162315, S.E. 11/09/2017). The subject implants have similar intended use, indications, and same materials as Primary Predicate 1 (K162315, S.E. 11/09/2017) and Predicate 2 (K172032, S.E. 11/20/2017). The subject and all predicate devices have similar scientific fundamental technology.</td>
<td></td>
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<thead>
<tr>
<th>Performance Data</th>
<th>Mechanical Testing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mechanical testing was conducted in accordance with the Guidance for Industry and FDA Staff - Spinal System 510(k)'s and provided in the Predicate 6 (K173125, S.E. 12/20/2017) submission. Additional Static Compression testing was completed as benchmark testing.</td>
<td></td>
</tr>
</tbody>
</table>
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.

**MRI Testing**

MRI testing was conducted in accordance with the Guidance for Industry and FDA Staff – Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment. The MRI testing was submitted and cleared in the Predicate 6 (K173125, S.E. 12/20/2017) submission.

The subject and Predicate 6 ø13mm centerpieces are identical in material and dimensions. Therefore, the subject ø13mm centerpieces do not present a new worst case and are justifiably classified as MR-Conditional.

<table>
<thead>
<tr>
<th>Performance Data</th>
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<tbody>
<tr>
<td>A clinical literature review was performed to support the use of the subject devices in the cervical spine. The risks of cervical use were identified and mitigated through design and surgical technique. Based on clinical literature, it was determined that the safety profile of the subject devices is equivalent to that of the predicate devices.</td>
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<tr>
<th>Conclusion</th>
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<tbody>
<tr>
<td>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:</td>
</tr>
<tr>
<td>• <strong>Primary Predicate 1</strong>- Globus FORTIFY Spacers (K162315, S.E. 11/09/2017)</td>
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<tr>
<td>Predicate</td>
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<tr>
<td>Predicate 2</td>
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<td>Predicate 3</td>
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<td>Predicate 4</td>
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<td>Predicate 5</td>
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<td>Predicate 6</td>
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