Dear Mr. O'Connor:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please
contact the Division of Industry and Consumer Education (DICE) 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. 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.

You may obtain other general information on your responsibilities under the Act from the
Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or
(301) 796-7100 or at its Internet address

Sincerely,

Mark N. Melkerson -S

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

Enclosure
510(k) Number *(if known)*
K172199

Device Name
ELEVATE™ Spinal System

**Indications for Use (Describe)**
The ELEVATE™ Spinal System Expandable Interbody Fusion Device is indicated for interbody fusion with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted via an open or a minimally invasive posterior approach. These implants are to be used with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone. These devices are intended to be used with supplemental fixation instrumentation, which has been cleared by the FDA for use in the lumbar spine.

**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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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."
Indications for Use

The CAPSTONE PTC™ Spinal System is indicated for interbody fusion with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone in patients with Degenerative Disc Disease (DDD) at one or two levels from L2 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment.

Additionally, the CAPSTONE PTC™ Spinal System is indicated to assist in the setting of spinal deformity as a supplement to pedicle screw fixation in patients diagnosed with degenerative scoliosis.

These implants may be implanted via an open or a minimally invasive posterior approach. Alternatively, these implants may also be implanted via an anterior and/or transforaminal approach. These implants are to be used with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone. These devices are intended to be used with supplemental fixation instrumentation, which has been cleared by the Food and Drug Administration (FDA) for use in the lumbar spine.

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

- [x] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)
Indications for Use

The CRESCENT™ Spinal System is indicated for interbody fusion with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone in patients with Degenerative Disc Disease (DDD) at one or two levels from L2 to S1. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants are to be used autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone. These devices are intended to be used with supplemental fixation instrumentation which has been cleared by the FDA for use in the lumbar spine.
Indications for Use

The CRESCENT™ Spinal System Titanium is indicated for interbody fusion with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants are to be used with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone. These devices are intended to be used with Medtronic supplemental fixation instrumentation which has been cleared by the FDA for use in the lumbar spine.

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)

Continued on a separate page if needed.

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510(k) SUMMARY

MEDTRONIC Sofamor Danek

ELEVATE™ Spinal System, CAPSTONE PTC™ Spinal System, CRESCENT™ Spinal System, and CRESCENT™ Spinal System Titanium

July 2017

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

Contact: Justin E. O’Connor
Regulatory Affairs Specialist

Date Prepared: July 20, 2017

II. Subject Device

Name of Device: ELEVATE™ Spinal System, CAPSTONE PTC™ Spinal System, CRESCENT™ Spinal System, and CRESCENT™ Spinal System Titanium

Regulation Number: 888.3080
Code: MAX
Classification Name: Intervertebral Fusion Device with Bone Graft, Lumbar
Classification: Class II
Common Name: Intervertebral Body Fusion Device
III. **Predicate Device:**

- K151128 (S.E. 08/06/2015) CAPSTONE® and CLYDESDALE® Spinal Systems – Predicate 1, Primary Predicate
- K142559 (S.E. 06/09/2015) ELEVATE™ Spinal System – Predicate 2, Additional Predicate
- K133205 (S.E. 03/13/2014) CAPSTONE PTC™ and CLYDESDALE PTC™ Spinal Systems – Predicate 3, Additional Predicate
- K094025 (S.E. 04/26/2010) CRESCENT™ Spinal System – Predicate 4, Additional Predicate
- K110543 (S.E. 08/09/2011) CRESCENT™ Spinal System Titanium – Predicate 5, Additional Predicate

The predicates have not been subject to a design related recall.

IV. **Device Description:**

**ELEVATE™ Spinal System**

The subject ELEVATE™ Spinal System consists of bullet nose expandable cages with teeth. The top of the cage is made of Polyetheretherketone (PEEK) and the base is made of Titanium Alloy (Ti--6Al-4V). The cages also contain Unalloy Tantalum markers, which allow for radiographic visualization during the surgical procedure. The ELEVATE™ implants are provided in both standard and an extra-lordotic design. The devices can be surgically implanted between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar intervertebral body fusion. The implants also contain hollow geometry which allows them to be packed with autogenous and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone.
CAPSTONE PTC™ Spinal System
The subject CAPSTONE PTC™ Spinal System consists of convex cages with a bullet nose and angular teeth. The implants are made of Polyetheretherketone (PEEK) and coated with Commercially Pure Titanium (CP Ti). The cages also contain Unalloy Tantalum markers, which allow for radiographic visualization during the surgical procedure. The CAPSTONE PTC™ implants are provided in various widths and heights, which can be inserted between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar interbody fusion surgeries. The hollow geometry of the implants allows them to be packed with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone.

CRESCENT™ Spinal System
The subject CRESCENT™ Spinal System consists of banana shaped cages with a bullet nose and angular teeth. The implants are made of Polyetheretherketone (PEEK) and contain Unalloy Tantalum markers, which allow for radiographic visualization during the surgical procedure. The CRESCENT™ implants are provided in various widths and heights, which can be inserted between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar interbody fusion surgeries. The hollow geometry of the implants allows them to be packed with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone.

CRESCENT® Spinal System Titanium
The subject CRESCENT™ Spinal System Titanium consists of banana shaped cages with a bullet nose and angular teeth. The CRESCENT™ Titanium implants are made of Titanium Alloy (Ti-6Al-4V) and are provided in various widths and heights, which can be inserted between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar interbody fusion surgeries. The hollow geometry of the implants allows them to be packed with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone.
V. **Indications:**

**ELEVATE™ Spinal System**

The ELEVATE™ Spinal System Expandable Interbody Fusion Device is indicated for interbody fusion with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted via an open or a minimally invasive posterior approach. These implants are to be used with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone. These devices are intended to be used with supplemental fixation instrumentation, which has been cleared by the FDA for use in the lumbar spine.

**CAPSTONE PTC™ Spinal System**

The CAPSTONE PTC™ Spinal System is indicated for interbody fusion with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone in patients with Degenerative Disc Disease (DDD) at one or two levels from L2 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. Additionally, the CAPSTONE PTC™ Spinal System is indicated to assist in the setting of spinal deformity as a supplement to pedicle screw fixation in patients diagnosed with degenerative scoliosis. These implants may be implanted via an open or a minimally invasive posterior approach. Alternatively, these implants may also be implanted via an anterior and/or transforaminal approach. These implants are to be used with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone. These devices are intended to be used with supplemental fixation instrumentation, which has been cleared by the Food and Drug Administration (FDA) for use in the lumbar spine.
**CRESCENT™ Spinal System**

The CRESCENT™ Spinal System is indicated for interbody fusion with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone in patients with Degenerative Disc Disease (DDD) at one or two levels from L2 to S1. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants are to be used autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone. These devices are intended to be used with supplemental fixation instrumentation which has been cleared by the FDA for use in the lumbar spine.

**CRESCENT™ Spinal System Titanium**

The CRESCENT™ Spinal System Titanium is indicated for interbody fusion with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants are to be used with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone. These devices are intended to be used with Medtronic supplemental fixation instrumentation which has been cleared by the FDA for use in the lumbar spine.

**VI. Comparison of Technological Characteristics with the Predicate Devices:**

The technological principle for both the subject and predicate devices is lumbar interbody fusion to provide correction and stabilization during intervertebral body fusion procedures. The subject interbody cages are all manufactured from the same materials as their system predicates and are inserted into the disc space along with graft material to
facilitate fusion, using supplemental fixation, at one or two contiguous levels from L2-S1.

The subject and predicate interbody cages are sterilized via gamma irradiation and provided sterile to the end user. In order to satisfy the FDA Endotoxin requirements for this submission, a 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>, Transfusion and Infusion Assemblies and Similar Medical Devices.

The purpose of this 510(k) bundled submission is to expand the indications to allow the subject interbody cages to be used with allogenic bone graft comprised of cancellous and/or corticocancellous bone as an alternative graft material option. With the exception of the inclusion of allogenic bone graft to the modified indications, there have been no changes to subject interbody cages; therefore, they are substantially equivalent to their predicates.

VII. Discussion of Supporting Retrospective Clinical Data and Non-Clinical Testing:

Published retrospective clinical data for the lumbar interbody fusion devices was cleared by the FDA in Medtronic’s CAPSTONE® and CLYDESDALE® Spinal System (K151128, S.E. 08/06/2015). The retrospective clinical data demonstrated that the use of allogenic bone graft in combination with, or without, autogenous bone graft is commonly used in conjunction with interbody fusion devices and poses no new risks to patients. Because the subject devices have the same intended use, indications, and fundamental technology as the primary predicate devices, the retrospective clinical data cleared in K151128 still applies, and no additional clinical data is required as a result of this submission.
VIII. **Conclusion:**

The design features, materials used, manufacturing processes, and sterilization methods are equivalent to the cleared ELEVATE™, CAPSTONE PTC™, CRESCENT™, and CRESCENT™ Titanium devices, with the exception of expanding the indications to include the use of allogenic bone graft comprised of cancellous and/or corticocancellous bone as an alternative graft material option. The expanded indications sought after in this application are identical to those cleared in K151128 (S.E. 08/06/2015).