DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Medtronic Sofamor Danek USA, Inc.
Raphael McInnis
Manager, Regulatory Affairs
1800 Pyramid Place
Memphis, Tennessee 38132

September 26, 2017

Re: K171107
Trade/Device Name: CAPSTONE CONTROL™ Spinal System
CAPSTONE CONTROL PTC™ Spinal System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: September 11, 2017
Received: September 13, 2017

Dear Mr. McInnis:

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 http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mark N. Melkerson -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171107

Device Name
CAPSTONE CONTROL™ SPINAL SYSTEM
CAPSTONE CONTROL PTC™ Spinal System

Indications for Use *(Describe)*

The CAPSTONE CONTROL™ Spinal System, including the CAPSTONE CONTROL PTC™ Spinal System, is intended to be used in spinal fusion procedures for patients diagnosed with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2 to S1. 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. When used for these indications, the CAPSTONE CONTROL™ Spinal System is intended for use with supplemental fixation systems cleared for use in the lumbar spine.

Additionally, the CAPSTONE CONTROL™ Spinal System can be used to provide anterior column support in patients diagnosed with degenerative scoliosis as an adjunct to pedicle screw fixation.

These patients should be skeletally mature and have had six months of nonoperative treatment. The CAPSTONE CONTROL™ Spinal System is intended to be used with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft when the subject device is used as an adjunct to fusion. These implants may be implanted via an open or a minimally invasive posterior or transforaminal approach.

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 Sofamor Danek

CAPSTONE CONTROL™ SPINAL SYSTEM

September 2017

I. Submitter:

Medtronic Sofamor Danek, USA Inc.
1800 Pyramid Place
Memphis, Tennessee 38132
Telephone: (901) 396-3133
Fax: (901) 346-9738

Contact: Raphael McInnis
Regulatory Affairs Sr. Manager
Telephone: (901) 399-2057 (Direct)

Alternate Contact: Julie Bassett
Regulatory Affairs Program Manager
Telephone: (901) 399-3248 (Direct)

Date Prepared: September 25, 2017

II. Device:

Name of Device: CAPSTONE CONTROL™ Spinal System
CAPSTONE CONTROL PTC™ Spinal System

Common Name: Interbody cage, interbody fusion device

Classification Name: Intervertebral Body Fusion Device with bone graft (21 CFR 888.3080)

Class: II

Product Code: MAX

III. Predicate Devices:

CAPSTONE® Spinal System
Primary Predicate - K151128, SE 8/5/2015

CAPSTONE® Spinal System
Predicate #2 - K073291, SE 4/24/2008
CAPSTONE CONTROL™ Spinal System
Predicate #3 - K120368, SE 4/9/2012
CAPSTONE PTC™ Spinal System
Predicate #4 - K133205, SE 3/13/2014
DIVERGENCE-L™ Spinal System
Predicate #5 - K150135, SE 6/11/2015
SOVEREIGN® Spinal System
Predicate #6 - K122037, SE 3/22/2013

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

IV. Description of Devices

The subject CAPSTONE CONTROL™ Spinal System adds 24-degree lordotic PEEK cages with tantalum markers to the existing CAPSTONE CONTROL™ Spinal System. Both the predicate sizes, and including the subject 24-degree lordotic cages, will also be provided with a commercially pure titanium coating (CP Ti) on the opposing, endplate-contacting sides of the implant. The titanium coated interbody cages will be branded as the CAPSTONE CONTROL PTC™ Spinal System (PTC = Pure Titanium Coating) to differentiate the coated cages from the uncoated CAPSTONE CONTROL™ Spinal System cages. The titanium coating is identical to the coating on the predicate CAPSTONE PTC™ Spinal System implants (Predicate #4).

The subject instruments include 24-degree lordotic cam spreader trials that correspond to the subject 24-degree lordotic cages. The predicate and subject cam spreader trials, and other instruments used to facilitate the implantation of the uncoated CAPSTONE CONTROL™ Spinal System cages, will also be used with the CAPSTONE CONTROL PTC™ Spinal System.

The CAPSTONE CONTROL™ / CAPSTONE CONTROL PTC™ Spinal Systems consist of interbody fusion cages of 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 autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone.

The CAPSTONE CONTROL™ / CAPSTONE CONTROL PTC™ Spinal System cages are available in heights of 8mm to 18mm, lengths of 22mm, 27mm, and 32mm, and widths of 9mm or 10mm. The implants will be available with 0°, 6°, 12°, 18°, or 24° of lordosis. The CAPSTONE CONTROL™ / CAPSTONE CONTROL PTC™ Spinal Systems also include cam spreader trials and a variety of instruments to help facilitate the implantation of the interbody fusion cages.

V. Indications for Use:

The indications for use for the CAPSTONE CONTROL™ / CAPSTONE CONTROL PTC™ are identical to the indications for use cleared for the primary predicate, CAPSTONE® Spinal System in K151128 (SE 8/5/2015). The indications for use are as follows:

> The CAPSTONE CONTROL™ Spinal System, including the CAPSTONE CONTROL PTC™ Spinal System, is intended to be used in spinal fusion procedures for patients diagnosed with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2 to S1. 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. When used for these indications, the CAPSTONE CONTROL™ Spinal System is intended for use with supplemental fixation systems cleared for use in the lumbar spine.

Additionally, the CAPSTONE CONTROL™ Spinal System can be used to provide anterior column support in patients diagnosed with degenerative scoliosis as an adjunct to pedicle screw fixation.

These patients should be skeletally mature and have had six months of nonoperative treatment. The CAPSTONE CONTROL™ Spinal System is intended to be used with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft when the subject device is used as an adjunct to fusion. These implants may be implanted via an open or a minimally invasive posterior or transforaminal approach.

VI. Comparison of Technological Characteristics with the Predicate Devices:

The CAPSTONE CONTROL™ / CAPSTONE CONTROL PTC™ Spinal Systems' interbody cages and cam spreader trials have the same intended use, materials, design features, and fundamental technology as their respective predicate devices:

CAPSTONE® Spinal System
Primary Predicate - K151128, SE 8/5/2015
CAPSTONE® Spinal System
Predicate #2 - K073291, SE 4/24/2008
CAPSTONE CONTROL™ Spinal System
Predicate #3 - K120368, SE 4/9/2012
CAPSTONE PTC™ Spinal System
Predicate #4 - K133205, SE 3/13/2014
DIVERGENCE-L™ Spinal System
Predicate #5 - K150135, SE 6/11/2015
SOVEREIGN® Spinal System
Predicate #6 - K122037, SE 3/22/2013

For instance, the subject CAPSTONE CONTROL PTC™ interbody cages have the same overall design as the predicate CAPSTONE CONTROL™ interbody cages. The primary difference is the titanium coating. The predicate and subject interbody cages are intended to be surgically implanted between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar intervertebral body fusion. The cam spreader trials are used to assist the surgeon

in selecting the appropriate size cage to use for the patient and are available in all the same lengths and lordotic options as the implants.

VII. Performance Data:

The following performance data were provided in support of substantial equivalence:

Commercially Pure Titanium Coating Evaluation

The commercially pure titanium coating used on the subject CAPSTONE CONTROL PTC™ Spinal System implants and CAPSTONE PTC™ Spinal System implants (Predicate #4) were evaluated in accordance with FDA's *Guidance for FDA Reviewers/Staff, Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket Surveillance Requirements*, issued February 2, 2000, and evaluated in accordance with the following standards:

- **ASTM F1854**: *Standard test method for stereological evaluation of porous coatings on medical implants;*
- **ASTM F1160**: *Standard Test Method for Shear and Bending Fatigue Testing of Calcium Phosphate and Metallic Medical and Composite Calcium Phosphate/ Metallic Coatings;*
- **ASTM F1044**: *Standard test method for shear testing of calcium phosphate coatings and metallic coatings;*
- **ASTM F1147**: *Standard test method for tension testing of calcium phosphate & metallic coatings;*
- **EN ISO 3274**: *Geometrical Product Specification (GPS) – Surface Texture: Profile Method – Nominal Characteristics of Contact (stylus instruments);*
- **EN ISO 4287**: *Geometrical Product Specification (GPS) – Surface Texture: Profile Method –Terms, Definitions, and Surface Texture Parameters;* and
- **EN ISO 4288**: *Geometrical Product Specification (GPS) – Surface Texture: Profile Method – Rules and Procedures for the Assessment of Surface Texture.*

The predetermined acceptance criteria, established using predicate test data, were met for all tests.

Mechanical Testing

Medtronic has evaluated the subject devices in accordance with FDA's Guidance Document, *Class II Special Controls Guidance Document: Intervertebral Body Fusion Device*, issued June 12, 2007 to demonstrate substantial equivalence to the predicate devices.

Design verification testing was completed on the worst case subject 24-degree lordotic coated CAPSTONE CONTROL PTC™ implants in accordance with:

- **ASTM F2077**: *Test Methods for Intervertebral Body Fusion Devices*;
- **ASTM F2267**: *Standard Test Method for Measuring Load Induced Subsidence of Intervertebral Body Fusion Device Under Static Axial Compression*;
- **ASTM Draft Standard F.04.25.02.02**: *Static Push-out Test Method for Invertebral Body Fusion Devices;* and
- **ASTM F1877**: *Standard Practice for Characterization of Particles*.

Design verification testing consisted of the following tests:

- Static Compression
- Compression Fatigue
- Static Compression-Shear
- Compression-Shear Fatigue
- Subsidence
- Expulsion
- Wear Debris

For expulsion (push-out) testing, the subject 24-degree lordotic uncoated CAPSTONE CONTROL™ implants were also tested. The subject 24-degree lordotic CAPSTONE CONTROL PTC™ implants met the pre-determined acceptance criteria, established using predicate test data, for all tests.

Design Validation

Cadaver validation labs demonstrated that independent surgeons could insert and rotate the 24-degree implant without issue or failure of the implants or instruments. The cadaver validation labs demonstrated that the subject implants and instruments functioned as intended and user needs were met.

MRI Safety Evaluation

In accordance with the FDA Guidance "*Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment*" the subject 24-degree lordotic CAPSTONE CONTROL™ interbody cages and the subject CAPSTONE CONTROL PTC™ interbody cages were evaluated using a comparison to a worst-case device for MR-safety that had been tested in accordance with the following standards:

- **ASTM F2052**: *Standard test method for measurement of magnetically induced displacement force on passive implants in the magnetic resonance environment*;
- **ASTM F2213**: *Standard test method for measurement of magnetically induced torque on medical devices in the magnetic resonance environment*;
- **ASTM F2119**: *Standard test method for evaluation of MR image artifacts from passive implants*; and
- **ASTM F2182**: *Standard test method for measurement of radio frequency induced heating on or near passive implant during magnetic resonance imaging.*

For purposes of MR safety, the volume of metallic material, types of metallic material, and geometry of the implant were compared to a worst-case spinal system. Based on the performance and MR-Conditional classification of the worst case spinal system, it can be inferred that CAPSTONE CONTROL™ (24-degree lordosis) and CAPSTONE CONTROL PTC™ implants will behave in a similar (albeit reduced) manner relative to MRI issues compared to the worst-case system.

VIII. Conclusion:

Based on the risk analysis, test results, and additional supporting documentation provided in the pre-market notification, the subject CAPSTONE CONTROL™ Spinal System and CAPSTONE CONTROL PTC™ Spinal System are equivalent to the following predicates:

CAPSTONE® Spinal System
Primary Predicate - K151128, SE 8/5/2015
CAPSTONE® Spinal System
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