May 6, 2019

Medtronic Sofamor Danek USA, INC.
Mr. Justin O'Connor
Senior Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K190165
Trade/Device Name: Capstone Control™ Spinal System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: January 31, 2019
Received: January 31, 2019

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. 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,

for
CAPT Raquel Peat, PhD, MPH, USPHS
Director
Office of Health Technology 6
Office of Product Evaluation and Quality
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)*
K190165

Device Name
Capstone Control™ Spinal System

Indications for Use *(Describe)*
The Capstone Control™ Spinal System is intended to be used in spinal fusion procedures for patients diagnosed with Degenerative Disc Disease (DDD) at 1 or 2 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 6 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.

The 18mm Capstone Control™ Spinal System implant can only be implanted via a Posterior (PLIF) approach. When using the 18mm Capstone Control™ Spinal System implant, a minimum of 2 implants are required per spinal level.

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."

K190165 - 510(k) Summary

MEDTRONIC
Capstone Control™ Spinal System

April 2019

I. Submitter	Medtronic Sofamor Danek, USA Inc. 1800 Pyramid Place Memphis, Tennessee 38132 Telephone: (901)396-3133 Fax: (901) 346-9738
Contact Person	Justin O'Connor Sr. Regulatory Affairs Specialist Direct Telephone: (901)399-2480
Date Prepared	April 2019
II. Name of Device	Capstone Control™ Spinal System
Common Name	Intervertebral Body Fusion Device
Classification Name	Intervertebral Fusion Device with Bone Graft, Lumbar
Classification	Implants: Class II Instrument Trials: Class II
Product Codes	MAX (21 CFR 888.3080)
III. Predicate Devices	**Predicate 1 (Primary Predicate)**: Capstone Control™ Spinal System – K171107 (S.E. 09/26/2017) **Predicate 2 (Additional Predicate)**: Capstone Control™ Spinal System – K120368 (S.E. 04/09/2012) **Predicate 3 (Additional Predicate)**: Perimeter® Interbody Fusion Device – K090353 (S.E. 08/29/2009) **Predicate 4 (Additional Predicate)**: Capstone® Spinal System – K073291 (S.E. 04/24/2008)

IV. Description	The Capstone Control™ Spinal System consists of convex cages with a bullet nose and angular teeth. The implants are made of Polyetheretherketone. The cages also contain Unalloy Tantalum markers, which allow for radiographic visualization during the surgical procedure. The Capstone Control™ Interbody Fusion Devices are provided in various widths, heights, and lordosis, which can be inserted between two vertebral bodies to give support and correction during interbody fusion surgeries. The hollow geometry of the implants also allows the implants to be packed with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone.
V. Indications for Use	The Capstone Control™ Spinal System is intended to be used in spinal fusion procedures for patients diagnosed with Degenerative Disc Disease (DDD) at 1 or 2 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 6 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. The 18mm Capstone Control™ Spinal System implant can only be implanted via a Posterior (PLIF) approach. When using the 18mm Capstone Control™ Spinal System implant, a minimum of 2 implants are required per spinal level.
VI. Comparison of Technological	The subject CAPSTONE CONTROL™ Spinal System has the same intended use, indications, materials, technological characteristics, spinal location, surgical approach, and sterilization

Characteristics with the Predicate Devices	method as its predicates. Both the subject and predicate Capstone Control™ devices are based on the same technological characteristics of providing fusion support for patients diagnosed with Degenerative Disc Disease (DDD) at one to two contiguous levels from L2 to S1, as well as used to provide anterior column support in patients diagnosed with degenerative scoliosis as an adjunct to pedicle screw fixation. The only difference between the subject and predicate Capstone Control™ devices is the subject devices have a length, which falls outside the cleared range of the Capstone Control™ Spinal System but does not raise any issues of safety and effectiveness. Please see the **Substantial Equivalence** section of this submission for more detail.
VII. Performance Data	**Mechanical Testing** In order to demonstrate substantial equivalence, Medtronic used to following FDA guidance document: • Class II Special Controls Guidance Document: Intervertebral Body Fusion Device issued June 12, 2007 Design verification testing for the worst-case subject interbody fusion device was completed in accordance with the following: • ASTM F2077: Test Methods for Intervertebral Fusion Devices • ASTM F2267: Standard Test Method for Measuring Load Induced Subsidence of Intervertebral Body Fusion Device under Static Axial Compression The verification tests completed were the following: • Static compression (ASTM F2077) • Static compression-shear (ASTM F2077) • Compression fatigue (ASTM F2077) • Compression-shear fatigue (ASTM F2077) • Subsidence (ASTM F2267) The acceptance criteria was met for all tests. Please see the **Bench Performance Testing** section of this submission for more detail.

	Biocompatibility Identical to the predicate devices, the sterile interbody fusion devices in the subject devices are made of Polyetheretherketone (PEEK) and contain Unalloy Tantalum markers, which allow for radiographic visualization during the surgical procedure. The non-sterile trials in the subject devices are manufactured from stainless steel, which is identical to the material used to manufacture the instruments cleared in the predicate devices. The materials mentioned above are considered biocompatible due to their long history of clinical use in medical devices. **Bacterial Endotoxin Testing** The bacterial endotoxin test, also known as Limulus amebocyte lysate (LAL) test, was performed utilizing worst case subject interbody fusion devices to verify that the subject devices meet the 20 endotoxin units (EU)/device pyrogen limit specification. Testing was successfully performed, and it was confirmed that the subject devices 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. **Magnetic Resonance Imaging (MRI)** The subject interbody fusion devices are part of the Capstone Control™ Spinal System that was cleared as MR-Conditional in Primary Predicate 1 (K171107, S.E. 09/26/2017). In accordance with the Guidance for Industry and FDA Staff – Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment, Medtronic re-evaluated the MRI compatibilty of the subject implants and determined that they do not present a new worst case to the existing Capstone Control™ Spinal System. Therefore, the Capstone Control™ Spinal System with the addition of the subject interbody fusion devices, remains classified as MR-Conditional.
VIII. Conclusion	Based on the supporting evidence provided, Medtronic believes the subject devices are substantially equivalent to the below predicates, as well as, the 5th percentile of PLIF devices that have been cleared by the FDA for market release.

	• **Predicate 1 (Primary Predicate)**: Capstone Control™ Spinal System – K171107 (S.E. 09/26/2017) • **Predicate 2 (Additional Predicate)**: Capstone Control™ Spinal System – K120368 (S.E. 04/09/2012) • **Predicate 3 (Additional Predicate)**: Perimeter® Interbody Fusion Device – K090353 (S.E. 08/29/2009) • **Predicate 4 (Additional Predicate)**: Capstone® Spinal System – K073291 (S.E. 04/24/2008)