DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 13, 2017

Medtronic Sofamor Danek
Mr. Ankit Shah
Sr. Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38125

Re: K171468
Trade/Device Name: FUSE™ Spinal System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: May 17, 2017
Received: May 18, 2017

Dear Mr. Shah:

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 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 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)*

K171468

Device Name
FUSE™ Spinal System

Indications for Use *(Describe)*

The FUSE Cage is indicated for interbody fusion with autogenous bone graft 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. 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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FUSE™ Spinal System

510(k) Summary

May 2017

I. Submitter:

Medtronic Sofamor Danek USA, Inc
1800 Pyramid Place
Memphis, Tennessee 38132

Contact:
Ankit K. Shah
Sr. Regulatory Affairs Specialist
Telephone: (901) 344-1272
Fax: (901) 346-9738

Date Prepared May 17, 2017

II. Device

Proprietary Trade Name	FUSE™ Spinal System
Common Name	Intervertebral Body Fusion Device
Classification Names	Intervertebral Fusion with Bone Graft, Lumbar
Classification	Class II (Implants and Instruments)
Product Code	MAX (21 CFR 888.3080)
Predicates	FUSE Spinal System K121288, S.E. 06/29/2012 (Primary Predicate) Capstone Control™ Spinal System K120368, S.E. 04/09/2012, (Additional Predicate)

III. PRODUCT DESCRIPTION:

The FUSE™ Cage is a titanium interbody cage 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 autogenous bone graft. The implants may be

implanted via a posterior or transforaminal approach and the procedure may be open or minimally invasive. The implants can be implanted unilaterally. FUSE™ implants consist of pure titanium according to the standard ISO 5832-2 or ASTM F67. It is not allowed to use FUSE™ cages in direct connection with components of other manufacturers. FUSE™ cages are for single use only.

IV. INDICATIONS FOR USE:

The FUSE Cage is indicated for interbody fusion with autogenous bone graft 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. These devices are intended to be used with supplemental fixation instrumentation, which has been cleared by the FDA for use in the lumbar spine.

V. Comparison of Technological Characteristics

The subject FUSE™ Spinal System has the same indications, intended use, fundamental scientific technology and material as the previously FDA cleared predicate 1 (primary predicate) Fuse Cage (K121288, S.E. 06/29/2012) and Capstone Control™ Spinal System K120368, S.E. 04/09/2012.

VI. Performance Data

Biocompatibility

Identical to the primary predicate devices the implants in the subject FUSE™ Spinal System are provided in sterile form and are made using commercially pure titanium. The non-sterile instruments are manufactured using stainless steel and are identical to the materials used in the instruments cleared under the primary predicate. The materials used in the subject FUSE™ Spinal System implants and instruments have a long clinical

history of safe and effective use in similar commercially available medical devices. Therefore, no additional biocompatibility testing is required.

Mechanical Testing

The predicate Fuse Cage K121288 are 24.5mm in length whereas the subject FUSE™ Spinal System implants are 28mm and 31.5mm in length maintaining the same width and height as the predicate. The ASTM F2077 "Test Methods for Intervertebral Body Fusion Devices," defines a worst case intervertebral body fusion device with the smallest footprint and tallest height. Since we are not reducing the footprint it does not introduce a worst case. The mechanical strength and the expulsion resistance have been documented in a confirmatory engineering rationale.

Medtronic believes that the subject implants do not introduce a new worst case scenario and are substantially equivalent to the predicate device.

Non-Pyrogenicity Endotoxin Testing

The 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>, Medical Devices – Bacterial Endotoxin and Pyrogen Tests.

VII. Conclusion:

An engineering rationale and risk analysis has been completed for the change. Based on the engineering rationale, risk analysis and additional supporting documentation provided in this premarket notification, Medtronic believes the subject system demonstrates substantial equivalence to listed predicate devices.