March 23, 2020

Medtronic Sofamor Danek, USA Inc.
Ms. Mia Wiggins
Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K191788
Trade/Device Name: CAPSTONE™ Spinal System, CLYDESDALE PTC™ Spinal System, CRESCENT™ Spinal System, CRESCENT™ Spinal System Titanium, DIVERGENCE-L™ Anterior/Oblique Lumbar Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: February 24, 2020
Received: February 25, 2020

Dear Ms. Wiggins:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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, Ph.D.
Assistant Director (Acting)
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
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)*
K191788

Device Name
CAPSTONE™ Spinal System, CLYDESDALE PTC™ Spinal System, CRESCENT™ Spinal System, CRESCENT™ Spinal System Titanium, DIVERGENCE-L™ Anterior/Oblique Lumbar Fusion System

Indications for Use *(Describe)*

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

CLYDESDALE PTC™ SPINAL SYSTEM
The CLYDESDALE PTC™ Spinal System is designed to be used with autogenous bone graft to facilitate interbody fusion and is intended for use with supplemental fixation systems cleared for use in the lumbar spine. The CLYDESDALE PTC™ Spinal System is used for patients diagnosed 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 a minimally invasive lateral approach.

CRESCENT™ SPINAL SYSTEM
The CRESCENT® Spinal System is indicated for interbody fusion with autogenous bone graft 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 nonoperative treatment. These implants are to be used 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.

CRESCENT™ SPINAL SYSTEM TITANIUM
The CRESCENT Spinal System Titanium 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 are to be used with autogenous bone graft. 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.

DIVERGENCE-L™ ANTERIOR/OBLIQUE LUMBAR FUSION SYSTEM
The DIVERGENCE-L™ Anterior/Oblique Lumbar Fusion System Interbody cage is intended for interbody fusion in skeletally mature patients and is to be used with supplemental fixation instrumentation cleared for use in the lumbar spine. The DIVERGENCE-L™ Anterior/Oblique Lumbar Fusion System Interbody device is indicated for use 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. Additionally, the DIVERGENCE-L™ Anterior/ Oblique Lumbar Fusion System device is indicated for use in patients diagnosed with deformity conditions as an adjunct to fusion. These patients should have had six months of non- operative treatment. The DIVERGENCEL™ Anterior/ Oblique Lumbar Fusion System interbody device is intended to be used with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. The DIVERGENCE-L™ Anterior/Oblique Lumbar Fusion System interbody cage is also required to be used with autogenous bone graft. These implants may be implanted via a variety of open or minimally invasive approaches. These approaches include anterior and oblique.

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
MRI Update for Medtronic Intervertebral Body Fusion Device Systems
July 2019

Submitter:	Medtronic Sofamor Danek, USA Inc. 1800 Pyramid Place Memphis, Tennessee 38132 Telephone: (901)396-3133 Fax: (901) 346-9738
Contact Person:	Mia Wiggins Regulatory Affairs Specialist Direct Telephone: (901)399-2699
Date Prepared:	July 2, 2019
Name of Device:	**Medtronic Intervertebral Body Fusion Device Systems** (CAPSTONE™ Spinal System, CLYDESDALE PTC™ Spinal System, CRESCENT™ Spinal System, CRESCENT™ Spinal System Titanium, DIVERGENCE-L™ Anterior/Oblique Lumbar Fusion System)
Common Name:	Interbody Cages, Spacers
Trade Name:	CAPSTONE™ Spinal System CLYDESDALE PTC™ Spinal System CRESCENT™ Spinal System CRESCENT™ Spinal System Titanium DIVERGENCE-L™ Anterior/Oblique Lumbar Fusion System

Regulatory Class, Regulation Number, Regulation Name and Device Product Code:	• Class II • 21 CFR 888.3080 • Intervertebral Body Fusion Device • MAX
Predicate Devices:	• **Primary Predicate**- K073291 CAPSTONE® Spinal System (S.E. 04/24/2008) **Additional Predicates:** • **Predicate 2**- K082342 CAPSTONE® Spinal System (S.E. 09/12/2008) • **Predicate 3**- K082732 CAPSTONE® Spinal System (S.E. 10/16/2008) • **Predicate 4**- K094025 CRESCENT™ Spinal System (S.E. 04/26/2010) • **Predicate 5**- K110543 CRESCENT® Spinal System Titanium (S.E. 08/09/2011) • **Predicate 6**- K121760 CAPSTONE® Spinal System (S.E. 08/29/2012) • **Predicate 7**- K133205 CAPSTONE PTC™ SPINAL SYSTEM, CLYDESDALE PTC™ SPINAL SYSTEM (S.E. 03/13/2014) • **Predicate 8**- K133650 CAPSTONE® Spinal System (S.E. 12/20/2013) • **Predicate 9**- K172199 ELEVATE™ Spinal System, CAPSTONE PTC™ Spinal System, CRESCENT™ Spinal System, CRESCENT™ Spinal System Titanium (S.E. 09/19/2017) • **Predicate 10**- K150135 DIVERGENCE-L™ Anterior/Oblique Lumbar Fusion System (S.E. 06/11/2015) **Reference predicates only:** • K122037 MRI Update for PEEK Interbody Fusion Devices (S.E. 03/22/2013)

	• K171689 ARTiC-L™ 3D Ti Spinal System and ARTiC-XL™ 3D Ti Spinal System with TiONIC ™ Technology (S.E. 10/05/2017)
Description of Devices:	The Intervertebral Body Fusion Device Systems are intended for vertebral body fixation of the thoracic or lumbar spine during the development of a thoracic or lumbar spinal fusion. Lumbar interbody fusion devices are intended for stabilization use and to promote bone fusion during the normal healing process following surgical correction of disorders of the spine.
Indications for Use:	**CAPSTONE® SPINAL SYSTEM** The CAPSTONE® Spinal System is indicated for interbody fusion with autogenous bone graft 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 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. These devices are intended to be used with supplemental fixation instrumentation, which has been cleared by the FDA for use in the lumbar spine. **CLYDESDALE PTC™ SPINAL SYSTEM** The CLYDESDALE PTC™ Spinal System

	is designed to be used with autogenous bone graft to facilitate interbody fusion and is intended for use with supplemental fixation systems cleared for use in the lumbar spine. The CLYDESDALE PTC™ Spinal System is used for patients diagnosed 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 a minimally invasive lateral approach. **CRESCENT™ SPINAL SYSTEM** The CRESCENT® Spinal System is indicated for interbody fusion with autogenous bone graft 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. 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 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. 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. **DIVERGENCE-L™ ANTERIOR/OBLIQUE LUMBAR FUSION SYSTEM** The DIVERGENCE-L™ Anterior/Oblique Lumbar Fusion System Interbody cage is intended for interbody fusion in skeletally mature patients and is to be used with supplemental fixation instrumentation cleared for use in the lumbar spine. The DIVERGENCE-L™ Anterior/Oblique Lumbar Fusion System Interbody device is indicated for use 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. Additionally, the DIVERGENCE-L™ Anterior/Oblique Lumbar Fusion System device is indicated for use in patients diagnosed with deformity conditions as an adjunct to fusion. These patients should have had six months of non- operative treatment. The DIVERGENCEL™ Anterior/Oblique Lumbar Fusion System interbody device is intended to be used with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. The DIVERGENCE-L™ Anterior/Oblique Lumbar Fusion System interbody cage is also required to be used with autogenous bone graft. These implants may be implanted via a variety of open or minimally invasive approaches. These approaches include anterior and oblique.

Comparison of Technological Characteristics with the Predicate Devices:	The subject devices do not differ from the technological characteristics of the predicate devices.
Performance Data:	The following performance data were provided in support of substantial equivalence: **MR Safety Testing** In accordance with the FDA Guidance "Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment" the subject Medtronic Intervertebral Body Fusion Device Systems were evaluated for MR-safety 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" · **ASTM F2182–** "Standard test method for measurement of radio frequency induced heating on or near passive implant during magnetic resonance imaging" The Medtronic Intervertebral Body Fusion Device Systems have been labeled in accordance with **ASTM F2503** "Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment".

Conclusion:	Based on the supporting documentation provided in this premarket notification, the subject Intervertebral Body Fusion Device Systems are as safe and effective as the following predicates: • **Primary Predicate**- K073291 CAPSTONE® Spinal System (S.E. 04/24/2008) **Additional Predicates:** • **Predicate 2**- K082342 CAPSTONE® Spinal System (S.E. 09/12/2008) • **Predicate 3**- K082732 CAPSTONE® Spinal System (S.E. 10/16/2008) • **Predicate 4**- K094025 CRESCENT™ Spinal System (S.E. 04/26/2010) • **Predicate 5**- K110543 CRESCENT® Spinal System Titanium (S.E. 08/09/2011) • **Predicate 6**- K121760 CAPSTONE® Spinal System (S.E. 08/29/2012) • **Predicate 7**- K133205 CAPSTONE PTC™ SPINAL SYSTEM, CLYDESDALE PTC™ SPINAL SYSTEM (S.E. 03/13/2014) • **Predicate 8**- K133650 CAPSTONE® Spinal System (S.E. 12/20/2013) • **Predicate 9**- K172199 ELEVATE™ Spinal System, CAPSTONE PTC™ Spinal System, CRESCENT™ Spinal System, CRESCENT™ Spinal System (S.E. 09/19/2017) • **Predicate 10**- K150135 DIVERGENCE-L™ Anterior/Oblique Lumbar Fusion System (S.E. 06/11/2015) **Reference predicates only:** • K122037 MRI Update for PEEK Interbody Fusion Devices (S.E. 03/22/2013)

	• K171689 ARTiC-L™ 3D Ti Spinal System and ARTiC-XL™ 3D Ti Spinal System with TiONIC ™ Technology (S.E. 10/05/2017)