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, Incorporated
Mr. Lee Grant
Distinguished Regulatory Affairs Advisor
1800 Pyramid Place
Memphis, Tennessee 38132

August 6, 2015

Re: K151128
Trade/Device Name: CLYDESDALE® Spinal System and CAPSTONE® Spinal System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: June 30, 2015
Received: July 8, 2015

Dear Mr. Grant:

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" (21CFR 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 yours,

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)*
K151128

Device Name
CAPSTONE® Spinal System

Indications for Use *(Describe)*

The CAPSTONE® 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® Spinal System is intended for use with supplemental fixation systems cleared for use in the lumbar spine.

Additionally, the CAPSTONE® 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® 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 approach. Alternatively, these implants may also be implanted via an anterior and/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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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:

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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)*
K151128

Device Name
CLYDESDALE® Spinal System

Indications for Use *(Describe)*

The CLYDESDALE® Spinal System is intended to be used in interbody 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 CLYDESDALE® Spinal System is intended for use with supplemental fixation systems cleared for use in the lumbar spine.

Additionally, the CLYDESDALE® 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 CLYDESDALE® 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 a minimally invasive lateral 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)

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510(k) Summary – K151128

August 2015

Company:	Medtronic Sofamor Danek USA 1800 Pyramid Place Memphis, Tennessee 38132 Telephone: (901) 396-3133 Fax: (901) 346-9738
Contact:	Lee Grant Distinguished Regulatory Affairs Advisor
Common Name:	Lumbar interbody fusion device, interbody cage
Device Trade Name:	(1) CLYDESDALE® Spinal System; (2) CAPSTONE® Spinal System
Regulatory Class:	II
Regulation Number:	21CFR Section 888.3080
Classification Name(s):	Intervertebral Body Fusion Device
Product Code:	MAX
Predicate Devices:	Primary Predicate: CLYDESDALE® Spinal System (K133577, SE 09/26/14) Class II, 21 CFR 888.3080, MAX; Additional Predicate: CAPSTONE® Spinal System (K133650, SE 12/20/13) Class II, 21 CFR 888.3080, MAX

Description:

CLYDESDALE® Spinal System: The CLYDESDALE® Spinal System consists of PEEK 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 graft. The purpose of this 510(k) submission is to expand the indications of the CLYDESDALE® Spinal System to allow the device to be used with the aforementioned allogenic bone graft.

CAPSTONE® Spinal System: The CAPSTONE® Spinal System consists of PEEK cages, titanium alloy cages and titanium 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 graft. The CAPSTONE® Spinal System includes various instruments, including trials used to assist in placement of the implants. The purpose of this 510(k) submission is to expand the indications of the CAPSTONE® Spinal System to allow the device to be used with the aforementioned allogenic bone graft.

Indications for Use:

CLYDESDALE® Spinal System:

The CLYDESDALE® Spinal System is intended to be used in interbody 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 CLYDESDALE® Spinal System is intended for use with supplemental fixation systems cleared for use in the lumbar spine.

Additionally, the CLYDESDALE® 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 CLYDESDALE® 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 a minimally invasive lateral approach.

CAPSTONE® Spinal System: The CAPSTONE® 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® Spinal System is intended for use with supplemental fixation systems cleared for use in the lumbar spine.

Additionally, the CAPSTONE® 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® 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 approach. Alternatively, these implants may also be implanted via an anterior and/or transforaminal approach.

Summary of the Technological Characteristics: The purpose of this bundled 510(k) application is to allow for the usage of allogenic bone graft comprised of cancellous and/or corticocancellous bone graft to be allowed as a graft material option for these devices. All subject devices found within this bundled submission have the same fundamental scientific technology. They are intended to provide correction and stabilization during intervertebral body fusion procedures for the aforementioned indications. They are all manufactured from the same materials as their respective predicates and there have been no changes to the implants' designs. With the exception of the inclusion of the allogenic bone graft material option, there have been no changes to either system's offerings and they are therefore substantially equivalent to their predicates.

Identification of Legally Marketed Devices: The subject CLYDESDALE® Spinal System is identical in design to the CLYDESDALE® Spinal System cleared in K133577 (SE 09/26/14), the primary predicate for this set of implants. No new CLYDESDALE® Spinal System implants are contained in this application. The subject CAPSTONE® Spinal System implants included in this application are identical in design to the CAPSTONE® Spinal System implants cleared in K133650 (SE 12/20/13). The aforementioned K133650 CAPSTONE® Spinal System application serves as an additional predicate for the implants contained in this application. No new CAPSTONE® Spinal System implants are included in this application.

Discussion of Supporting Retrospective Clinical Data and Non-Clinical Testing: Published retrospective clinical data for the lumbar interbody fusion devices similar to the CLYDESDALE® Spinal System and the CAPSTONE® Spinal System were provided in support of this application. The published clinical outcomes demonstrated that the use of allogenic bone graft in interbody fusion procedures to treat the patient population referenced in the indications statement, poses no new risks to the patients. No changes were made to the existing devices, nor

were any new components added to the systems. Therefore, no additional testing was required or performed. This submission also referenced the ANATOMIC™ PEEK Cervical Fusion System (K130177), as it was recently cleared by the FDA for usage with allogenic bone graft.

Conclusion: The subject CLYDESDALE® Spinal System and the CAPSTONE® Spinal System are substantially equivalent to the primary predicate devices cleared in K133577 for the CLYDESDALE® Spinal System and in the additional predicate, K133650 application, for the CAPSTONE® Spinal System. The published clinical outcomes demonstrate these devices may be used with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft.