CLYDESDALE® Spinal System
510(k) Summary
December 10, 2013

DEC 1 1 2013

I.	**COMPANY:**	Medtronic Sofamor Danek USA, Inc. 1800 Pyramid Place Memphis, Tennessee 38132
II.	**CONTACT:**	Mr. Brad Sheals, MS Senior Regulatory Affairs Specialist Telephone: (901) 396-3133 Fax: (901) 346-9738
III.	**PROPRIETARY TRADE NAME:**	CLYDESDALE® Spinal System
IV.	**CLASSIFICATION NAME:**	Intervertebral Fusion with Bone Graft, Lumbar
	COMMON NAME:	Intervertebral Body Fusion Device
	CLASS:	II
	PRODUCT CODE:	MAX
	REGULATION NUMBER:	21 CFR 888.3080

V. PRODUCT DESCRIPTION:

The CLYDESDALE® Spinal System is intended to help provide support in the intervertebral body space during fusion of vertebral bodies in the lumbar spine. This system is intended to be used with supplemental fixation.

The CLYDESDALE® Spinal System consists of PEEK cages of various widths and heights, which include tantalum markers. These devices 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 allow them to be packed with autogenous bone graft.

The purpose of this 510(k) submission includes additional implant sizes and trials for the CLYDESDALE® Spinal System. The subject implants will be offered in 18mm, 22mm, 26mm widths, 0°, 8°, 12°, 18° of lordosis and 8mm, 10mm, 12mm, 16mm, 18mm, 20mm heights, and in the same lengths as the predicate CLYDESDALE® Spinal System, K100175 (S.E. 06/02/2010).

VI. INDICATIONS FOR USE:

The CLYDESDALE® 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® 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.

VII. SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS:

The purpose of this Traditional 510(k) submission is to seek clearance of additional implant sizes and trials into the CLYDESDALE® Spinal System family. The design, materials and fundamental technology are the same as the current CLYDESDALE® Spinal System.

VIII. IDENTIFICATION OF LEGALLY MARKETED DEVICES USED TO CLAIM SUBSTANTIAL EQUIVALENCE:

The design features and indications for use for the subject CLYDESDALE® Spinal System are substantially equivalent to the following predicates:

- CLYDESDALE® Spinal System, K100175, (S.E. 06/02/2010)
- PERIMETER™ Spinal System, K090353, (S.E. 09/29/2009)
- CAPSTONE CONTROL™ Spinal System, K120368 (S.E. 04/09/2012)
- CAPSTONE® Spinal System K073291, (S.E. 04/24/2008)
- CoRoent® System K071795, (S.E. 12/04/2007)

IX. DISCUSSION OF NON-CLINICAL TESTING:

An assessment of the subject CLYDESDALE® Spinal System was completed in accordance with Medtronic design control processes.

Mechanical Testing was conducted according to FDA's guidance document, "Class II Special Controls Guidance Document: Intervertebral Body Fusion Device". For a determination of substantial equivalence, the following non-clinical mechanical tests were performed:

Tests Performed	Applicable Standards
Static Compression- Shear	ASTM F2077 (Test Methods for Intervertebral Body Fusion Devices)
Compression- Shear Fatigue	

The subject implants met the acceptance criteria. Based on the results, the subject implants demonstrated that they are as safe, as effective and perform as well as the predicate device(s).

X. DISCUSSION OF CLINICAL TESTING:

No clinical testing was required.

XI. CONCLUSIONS DRAWN FROM THE NON-CLINICAL TESTING:

Based on the risk assessment, test results and additional supporting documentation provided in this premarket notification, Medtronic believes the subject CLYDESDALE® Spinal System demonstrates substantial equivalence to the listed predicate devices.

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

December 11, 2013

Medtronic Sofamor Danek USA, Incorporated
Brad Sheals, MS
Senior Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K132897
Trade/Device Name: CLYDESDALE® Spinal System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: September 13, 2013
Received: September 16, 2013

Dear Mr. Sheals:

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K132897

Device Name: CLYDESDALE® Spinal System

Indications for Use:

The CLYDESDALE® 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® 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.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD
Division of Orthopedic Devices