DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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December 14, 2016

Medtronic Sofamor Danek USA, Inc.
% Kanesha Hines
Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K162680
Trade/Device Name: SOVEREIGN® Spinal System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVD
Dated: September 23, 2016
Received: September 26, 2016

Dear Ms. Hines:

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)*
K162680

Device Name
SOVEREIGN® Spinal System

Indications for Use *(Describe)*

The SOVEREIGN® Spinal System is indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. 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 6 months of non-operative treatment. These implants may be implanted via a variety of open or minimally invasive approaches. These approaches include anterior and oblique.

The SOVEREIGN® interbody system may be used as a stand-alone device or in conjunction with supplemental fixation. When used as a stand-alone device, the SOVEREIGN® interbody device is intended to be used with 3 titanium alloy fixed or variable angle screws. The accompanying cover plate MUST be used anytime the device is used with any number of variable angle screws. If the physician chooses to use less than 3 or none of the provided screws, additional supplemental fixation in the lumbar spine must be used to augment stability.

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
SOVEREIGN® Spinal System

December 2016

Submitter:	Medtronic Sofamor Danek USA, Inc. 1800 Pyramid Place Memphis, Tennessee 38132 Telephone: (901)396-3133 Fax: (901) 346-9738
Contact Person	Kanesha Hines Regulatory Affairs Specialist Direct Telephone: (901)399-2670
Date Prepared	December 9, 2016
Name of Device	SOVEREIGN® Spinal System
Common Name	Intervertebral Body Fusion Device
Trade Name	SOVEREIGN® Spinal System
Regulatory Class, Regulation Number, Regulation Name, and Device Product Code	• Class II • 21 CFR 888.3080 Intervertebral Body Fusion Device; OVD
Predicate Devices	K121982 SOVEREIGN® Spinal System (S.E. 07/06/2012) – Primary Predicate K150135 DIVERGENCE-L™ Anterior Oblique Lumbar Fusion System (S.E. 06/11/2015) *The predicates have not been subject to a design related recall.*
Description of Devices	The SOVEREIGN® Spinal System consists of interbody cages, screws, coverplates, instruments, and accessories. The subject instruments include: • Trial Handle • Trials • Coverplate Inserter • Interbody Inserters
Indications for Use	The SOVEREIGN® Spinal System is indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. 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 6 months of non-operative treatment. These implants may be implanted via a variety of open or minimally invasive approaches. These approaches include anterior and oblique. The SOVEREIGN® interbody system may be used as a stand-alone device or in conjunction with supplemental fixation. When used as a stand-alone device, the SOVEREIGN® interbody device is intended to be used with 3 titanium alloy fixed or variable angle screws. The accompanying cover plate MUST be used anytime the device is used with any number of variable angle screws. If the physician chooses to use less than 3 or none of the provided screws, additional supplemental fixation in the lumbar spine must be used to augment stability.
Comparison of Technological Characteristics with the Predicate Devices:	The primary predicate for the SOVEREIGN® Spinal System is part of the predicate SOVEREIGN® Spinal System (K121982 – S.E. 07/06/2012), while Predicate 2 is part of the DIVERGENCE-L™ Anterior Oblique Lumbar Fusion System (K150135 – S.E. 06/11/2015). • **(Primary) Predicate 1 (K121982, S.E 07/06/2012) SOVEREIGN® Spinal System**-This predicate is a design predicate for the trial handle, trials, coverplate inserter, and the interbody inserters. This predicate has identical sizes, sterilization method, materials, and intended use. Additionally, this predicate has similar indications, surgical technique, overall design, and fundamental technology as the subject instruments. • Predicate 2 (K150135, S.E 06/11/2015) DIVERGENCE-L™ Anterior Oblique Lumbar Fusion System- This predicate is a design predicate for the subject trial handle, trials, and oblique indication. This predicate has identical materials, sterilization method, thread size, thread length, overall instrument length, surgical approach, and fundamental technology. Additionally, this predicate has similar indications, intended use, and surgical technique as the subject trial handle and trials.

Performance Data:	The following performance data were provided in support of substantial equivalence. **Validation Testing** A pre-clinical validation study was conducted in spine models which demonstrated that the proposed instruments could be used as intended. **Mechanical Testing** In accordance with the Guidance for Industry and FDA Staff – Spinal System 510(k)'s, Medtronic has evaluated the subject devices to demonstrate substantial equivalence to the predicate devices. Medtronic believes that testing is not warranted for the subject instruments as they do not present a new worst case when compared to the predicate instruments as outlined within the Bench Performance Section.
Conclusion:	Based on the supporting documentation provided in this pre-market notification, the subject SOVEREIGN® Spinal System instruments are as safe and effective as the following predicates: • K121982 SOVEREIGN® Spinal System (S.E. 07/06/2012) – (Primary Predicate) • K150135 DIVERGENCE-L™ Anterior Oblique Lumbar Fusion System (S.E. 06/11/2015)