August 30, 2021

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

Re: K172328
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

Dear Ms. Hines:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated November 2, 2017. Specifically, FDA is updating this SE Letter as an administrative correction, to update the Indications for Use and labeling.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Brent Showalter, Ph.D., OHT6: Office of Orthopedic Devices, (240) 402-1840, Brent.Showalter@fda.hhs.gov.

Sincerely,

Brent Showalter -S

Brent L. Showalter, Ph.D.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

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

November 2, 2017

Re: K172328
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: October 3, 2017
Received: October 4, 2017

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 (DICE) 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 (DICE) 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K172328

Device Name
Sovereign™ Spinal System

Indications for Use *(Describe)*
The Sovereign™ Spinal System is indicated for use with autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate 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. Additionally, the Sovereign™ Spinal System is indicated for use in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity conditions as an adjunct to fusion. These patients should be skeletally mature and have had 6 months of non-operative treatment. When used in patients as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity conditions, additional supplemental fixation (e.g. posterior fixation) must be used. These implants may be implanted via a variety of open or minimally invasive approaches. These approaches include anterior and oblique.

The Sovereign™ Spinal System may be used as a stand-alone device or in conjunction with supplemental fixation. When used as a stand-alone device, the Sovereign™ Spinal System 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. Implants with lordosis angles greater than 18° are intended to be used with supplemental fixation (e.g. facet screws or posterior fixation).

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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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

MEDTRONIC
SOVEREIGN™ Spinal System

August 2021

Submitter:	Medtronic Sofamor Danek, USA Inc. 1800 Pyramid Place Memphis, Tennessee 38132 Telephone: (901)396-3133 Fax: (901) 346-9738
Contact Person	Raphael McInnis Sr. Regulatory Affairs Manager Direct Telephone: (901)399-2057
Date Prepared	August 6, 2021
Name of Device	SOVEREIGN™ Spinal System
Common Name	Intervertebral body fusion device
Classification Name	Intervertebral Body Fusion Device: 21 CFR 888.3080
Classification	Class II
Product Codes	OVD 21 CFR 888.3080
Predicate Devices	There are 9 Predicates. **Primary Predicate 1-** SOVEREIGN™ Spinal System (K091813, S.E 11/17/2009) **Predicate 2-** DIVERGENCE-L™ Anterior/Oblique Lumbar Fusion System (K150135, S.E. 06/11/2015) **Predicate 3-** BASE Interfixated Titanium System (K170592, S.E 04/26/2017) **Predicate 4-** CLYDESDALE™ PTC Spinal System (K133205, S.E. 03/13/2014) **Predicate 5-** SOVEREIGN™ Spinal System (K162680, S.E. 12/14/2016) **Predicate 6-** DIVERGENCE-L™ Anterior/Oblique Lumbar Fusion System (K162212, S.E. 05/19/2017)

	Predicate 7- CLYDESDALE™ Spinal System (K132897 S.E. 12/11/2013) **Predicate 8-** LT-CAGE™ PEEK Lumbar Tapered Fusion Device (P970015, 05/14/1999)* **Predicate 9-** SOVEREIGN™ Spinal System (K122037, S.E. 03/22/2013) * The LT-CAGE™ PEEK Lumbar Tapered Fusion Device falls within the category of a Class II (Special Controls) Cervical Interbody Fusion Device due to the FDA down classification of cages from a Class III device to a Class II[1]. The predicate device is a cage/interbody device used for anterior cervical interbody fusion procedures. The predicate components have been tested and found to be substantially equivalent to previously approved cages such as the AFFINITY® Anterior Cervical Cage (titanium), the PEEK PREVAIL™ Cervical Interbody Device and the BAK/C® Cervical Interbody Fusion System. [1] Guidance for Industry and FDA Staff – Class II Special Controls Guidance Document: Intervertebral Body Fusion Device. Document issued on: June 12, 2007. *The predicates have not been subject to a design related recall.*
Description of Devices	The SOVEREIGN™ Spinal System is an intervertebral body fusion device with internal screw fixation. The subject devices in this submission add additional polyetheretherketone (PEEK) implant lordosis options with corresponding trials and PTC implant options with a Commercially Pure Titanium (CP Ti) coating, to the existing SOVEREIGN™ Spinal System.
Indications for Use	<u>SOVEREIGN™ Spinal System</u> *The SOVEREIGN™ Spinal System is indicated for use with autogenous bone graft and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate 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. Additionally, the SOVEREIGN™ Spinal System is indicated for use in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity conditions as an adjunct to fusion. These patients should be skeletally mature and have had 6 months of non-operative treatment. When used in patients as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity conditions, additional supplemental fixation (e.g. posterior fixation) must be used. 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. Implants with lordosis angles greater than 18° are intended to be used with supplemental fixation (e.g. facet screws or posterior fixation).*
Comparison of Technological Characteristics with the Predicate Devices	<u>SOVEREIGN™ Spinal System Implants</u> The primary predicate for the SOVEREIGN™ Spinal System is the predicate SOVERIGN™ Spinal System (K091813, S.E 11/17/2009). The subject SOVEREIGN™ Spinal System devices have identical intended use and similar indications and similar materials as the following FDA cleared Primary Predicate 1 K091813 (S.E 11/17/2009), Predicate 2 K150135 (S.E. 06/11/2015), Predicate 3 K170592 (S.E. 04/26/2017), Predicate 6 K162212 (S.E. 05/19/2017), Predicate 7 K132897 (S.E. 12/11/2013), Predicate 8 P970015 (05/14/1999), and Predicate 9 K122037 (S.E. 03/22/2013). The predicate and subject devices have the identical function and similar scientific fundamental technology. <u>SOVEREIGN™ PTC Spinal System Implants</u> The primary predicate for the SOVEREIGN™ Spinal System is the predicate SOVERIGN™ Spinal System (K091813, S.E 11/17/2009). The subject SOVEREIGN™ Spinal System devices have identical intended use and similar indications and similar materials as the following FDA cleared Primary Predicate 1 K091813 (S.E 11/17/2009), Predicate 2 K150135 (S.E. 06/11/2015), Predicate 3 K170592 (S.E. 04/26/2017), Predicate 4 K133205 (S.E. 03/13/2014), Predicate 6 K162212 (S.E. 05/19/2017), Predicate 7 K132897 (S.E. 12/11/2013), Predicate 8 P970015 (05/14/1999), and Predicate 9 K122037 (S.E. 03/22/2013). The predicate and subject devices have the identical function and similar scientific fundamental technology.

	SOVEREIGN™ Spinal System Instruments The subject trials are identical in intended use and material as its predicate in Predicate 5 K162680 (S.E 12/14/2016). The difference between the subject and predicate trials is that the subject trials are designed for the sizes of the subject implants.
Performance Data	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. Design verification testing for the subject implants was completed in accordance with - ASTM F2077, Test Methods For Intervertebral Body Fusion Devices - ASTM F2267, Standard Test Method for Measuring Load Induced Subsidence of Intervertebral Body Fusion Device Under Static Axial Compression - ASTM Draft Standard F-04.25.02.02, Static Push-out Test Method for Intervertebral Body Fusion Devices The tests completed were: - Static Compression - Compression Fatigue - Static Compression Shear - Compression Shear Fatigue - Subsidence -Expulsion The subject implants met the pre-determined acceptance criteria for all tests. Therefore, Medtronic believes design verification testing demonstrated that the subject implants are substantially equivalent to the predicate Medtronic 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 devices.

	MRI Testing In accordance with the Guidance for Industry and FDA Staff – Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment, Medtronic has evaluated the subject devices to demonstrate substantial equivalence to the predicate devices. Medtronic believes that the subject instruments do not present a new worst case and thus, can justifiably be classified as MR-Conditional.
Conclusion	Based on the test results and additional supporting information provided in this premarket notification, Medtronic believes the subject devices are at least as safe as and effective as the legally marketed predicate devices: • Primary Predicate 1- SOVEREIGN™ Spinal System (K091813, S.E 11/17/2009) • Predicate 2- DIVERGENCE-L™ Anterior/Oblique Lumbar Fusion System (K150135, S.E. 06/11/2015) • Predicate 3- BASE Interfixated Titanium System (K170592, S.E 04/26/2017) • Predicate 4- CLYDESDALE™ PTC Spinal System (K133205, S.E. 03/13/2014) • Predicate 5- SOVEREIGN™ Spinal System (K162680, S.E. 12/14/2016) • Predicate 6- DIVERGENCE-L™ Anterior/Oblique Lumbar Fusion System (K162212, S.E. 05/19/2017) • Predicate 7- CLYDESDALE™ Spinal System (K132897 S.E. 12/11/2013) • Predicate 8- LT-CAGE™ PEEK Lumbar Tapered Fusion Device (P970015, 05/14/1999) • Predicate 9- SOVEREIGN™ Spinal System (K122037, S.E. 03/22/2013)