July 14, 2026

Medtronic Sofamor Danek USA, Inc.
Kelly McDonnell
Sr. Principal Regulatory Affairs Specialist
1800 Pyramid Pl.
Memphis, Tennessee 38132

Re: K261020
Trade/Device Name: Symmetrix™ L Spinal System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: June 15, 2026
Received: June 15, 2026

Dear Kelly McDonnell:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

Brent 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

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261020

Please provide the device trade name(s).

Symmetrix™ L Spinal System

Please provide your Indications for Use below.

The Symmetrix™ L Spinal System is indicated for spinal fusion procedures from T1 to S1 in skeletally mature patients with symptomatic Degenerative Disc Disease (DDD, defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies), degenerative spondylolisthesis, spinal stenosis, failed previous fusion (pseudarthrosis), and/or disc herniation (with myelopathy and/or radiculopathy with or without axial pain) at one or two contiguous levels. Additionally, the Symmetrix™ L Spinal System can be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity. Patients should have had six months of nonoperative treatment prior to treatment with this device. The Symmetrix™ L Spinal System is intended to be used with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft, demineralized allograft bone with bone marrow aspirate, and/or bone void filler cleared for use within the intervertebral body space to facilitate fusion. The Symmetrix™ L Spinal System is intended to be used with supplemental fixation cleared for use in the thoracic and/or lumbar spine.

Please select the types of uses (select one or both, as applicable).

- [x] Prescription Use (21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

Please select the age group(s) for which the device(s) is to be used.

- [ ] Neonates/Newborns (Birth to < 29 days old)
- [ ] Infants (29 days old to < 2 years old)
- [ ] Children (2 years old to < 12 years old)
- [ ] Adolescents (12 years old to < 22 years old)
- [x] Adults (22 years old and greater)

510(k) Summary
MEDTRONIC Sofamor Danek USA, Inc.

I. Submitter

Medtronic Sofamor Danek, USA Inc.
1800 Pyramid Place
Memphis, Tennessee 38132

Contact: Kelly McDonnell
Sr. Principal Regulatory Affairs Specialist
Email: kelly.m.mcdonnell@medtronic.com

Date Prepared: July 13, 2026

II. Device Name

Trade Name: Symmetrix™ L Spinal System

Common name: Intervertebral body fusion device

Classification: Class II

Product Codes: MAX (21 CFR 888.3080) Intervertebral body fusion device

Panel: Orthopedic

III. Predicate Devices:

Primary Predicate: Anteralign™ TL Spinal System K212524 (S.E. 12/08/2021)

Additional Predicates:

- ARTiC-L 3D Ti Spinal System with TiONIC Technology, ARTiC-XL 3D Ti Spinal System with TiONIC Technology K171689 (S.E. 10/05/2017)
- IdentiTi™ II Interbody System K242364 (S.E. 10/04/2024)

The predicate devices were not subjected to any Recall.

IV. Description

The Symmetrix™ L Spinal System implants are interbody fusion devices that feature a macroporous gyroid lattice structure core with a footprint-optimized design intended to maximize contact with the apophyseal ring. Interbodies are provided in various widths, lengths, heights, and lordotic angles to accommodate different patient anatomy. Interbodies have a central graft chamber that allows for packing of graft to aid in the promotion of fusion. The lattice structure of the Symmetrix™ L Spinal System interbodies have an apparent modulus comparable to cancellous bone. The Symmetrix™ L Spinal System interbodies also feature macro and microroughened porous endplates to resist expulsion. The Symmetrix™ L Spinal System incorporate an interconnected lattice designed to achieve biological fixation, and promote fusion through the interbody. Interbodies are additively manufactured from titanium powder and are provided packaged, sterilized by radiation.

V. Indications for use

The Symmetrix™ L Spinal System is indicated for spinal fusion procedures from T1 to S1 in skeletally mature patients with symptomatic Degenerative Disc Disease (DDD, defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies), degenerative spondylolisthesis, spinal stenosis, failed previous fusion (pseudarthrosis), and/or disc herniation (with myelopathy and/or radiculopathy with or without axial pain) at one or two contiguous levels. Additionally, the Symmetrix™ L Spinal System can be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity. Patients should have had six months of nonoperative treatment prior to treatment with this device. The Symmetrix™ L Spinal System is intended to be used with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft, demineralized allograft bone with bone marrow aspirate, and/or bone void filler cleared for use within the intervertebral body space to facilitate fusion. The Symmetrix™ L Spinal System is intended to be used with supplemental fixation cleared for use in the thoracic and/or lumbar spine.

VI. Comparison of Technological Characteristics with the Predicate Devices

The Symmetrix™ L Spinal System has the same intended use, principle of operation, material, sterilization and similar design, sizing, manufacturing, and indications as the identified predicate devices. Based on these comparisons presented in the submission, the Symmetrix™ L Spinal System demonstrates substantial equivalence to the predicate devices.

VII. Performance Data

Mechanical Testing:

Bench testing was conducted in accordance with ASTM F2077, F2267, and draft F-04.25.02.02 consistent with expected testing per "Guidance for Industry and FDA Staff – Spinal System 510(k)'s." Results demonstrated mechanical performance comparable to acceptance criteria derived from the predicate devices. MRI safety evaluation was conducted the implants were adopted into previously conducted validation testing, which are labeled MR Conditional.

- Static and fatigue compression
- Static and fatigue compression-shear
- Push-out force
- Subsidence resistance

Biocompatibility:

Interbody implants are permanent (>30 days) tissue- and bone-contacting devices in accordance with FDA guidance applying ISO 10993-1. The implants are manufactured from titanium alloy compliant with ASTM F3001, identical to the predicate devices. Based on material composition and long-standing clinical use of the same materials and manufacturing process in the predicates, additional biocompatibility testing is not required.

- ASTM F3001 - Standard Specification for Additive Manufacturing Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) with Powder Bed Fusion

The associated surgical instruments are non-implant devices intended for limited-duration (<24 hours) tissue- and bone-contact. The instruments are manufactured from the stainless steel compliant with ASTM A564, consistent with the predicate instruments. Based on material composition, manufacturing process, contact duration, and clinical history, additional biocompatibility testing is not required.

- ASTM A564 - Standard Specification for Hot-Rolled and Cold-Finished Age-Hardening Stainless Steel Bars and Shapes

VIII. Conclusion

The Symmetrix™ L Spinal System is substantially equivalent to the identified predicates with respect to intended use, technological characteristics, materials, performance, safety, and effectiveness.

- Primary: Anteralign™ TL Spinal System K212524 (S.E. 12/08/2021)
- Additional:
  - ARTiC-L 3D Ti Spinal System with TiONIC Technology, ARTiC-XL 3D Ti Spinal System with TiONIC Technology K171689 (S.E. 10/05/2017)
  - IdentiTi™ II Interbody System K242364 (S.E. 10/04/2024)