October 29, 2026

Medtronic Sofamor Danek USA, Inc.
Elizabeth Hamilton
Sr. Regulatory Affairs Specialist
1800 Pyramid Pl.
Memphis, Tennessee 38132

Re: K262572
Trade/Device Name: Symmetrix™ PX Spinal System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: October 2, 2026
Received: October 2, 2026

Dear Elizabeth Hamilton:

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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 Office of Industry and Consumer Education (OICE) to ask a question about a specific regulatory topic. See the OICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-office-industry-and-consumer-education-oice) for more information or contact OICE by email (AskOICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

KATHERINE D.
KAVLOCK -S

for
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.	K262572

Please provide the device trade name(s).

Symmetrix™ PX Spinal System

Please provide your Indications for Use below.

Symmetrix™ PX Spinal cages with or without macro-, micro-, and nano-roughened surface textured features are intended to be used at one or two contiguous levels of the lumbar spine (L2-S1) in spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD - defined by discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies), degenerative spondylolisthesis, and/or spinal stenosis.These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the levels involved. Additionally, the Symmetrix™ PX Spinal System can be used with patients diagnosed with spinal deformities as an adjunct to fusion. These patients should be skeletally mature and have undergone 6 months of non-operative treatment prior to surgery. Implants are used to facilitate fusion in the lumbar spine using autogenous bone graft and/or allograft bone graft comprised of cancellous and/or corticocancellous bone, and/or demineralized allograft bone with bone marrow aspirate to facilitate fusion. These implants are intended for use with supplemental internal fixation systems.

Please select the types of uses.

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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

I. Submitter

Medtronic Sofamor Danek, USA Inc.
1800 Pyramid Place
Memphis, Tennessee 38132
Contact: Elizabeth Hamilton
Sr. Regulatory Affairs Specialist
Phone: (901) 396-3133
Email: elizabeth.c.hamilton@medtronic.com
Date Prepared: July 24, 2026

II. Device Name

Trade Name: Symmetrix™ PX Spinal System

Common name: Implants: Intervertebral body fusion device (Implants: cage, spacer)
Instruments: Navigated instruments

Classification: Class II

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

Panel: Orthopedic

III. Predicate Devices:

Primary Predicate:
Catalyft™ PL Expandable Interbody System (K210425 S.E. 05/24/2021, K253011 S.E. 07/17/2026)
Additional Predicate: Catalyft™ LS Expandable Interbody System with Titan nanoLOCK Surface Technology (K241992 S.E. 10/28/2024, K223153 S.E. 12/16/2022)
Additional Predicate: Adaptix Interbody System with Titan nanoLOCK Surface Technology (K201267, S. E.8/26/20, K250669 S.E. 4/22/2025)
Additional Predicate: Globus Rise Spacer (K152022 S.E. 2/10/2017)

IV. Device Description

The Symmetrix™ PX Spinal System consists of expandable interbodies manufactured from titanium alloy, cobalt chromium alloy, and polyetheretherketone (PEEK), offered in various widths, lengths, heights and adjustable lordotic angles to accommodate patient anatomy as well as offerings that incorporate Titan Surface Technology with macro-, micro-, and nano-roughened surface textures. These devices can be inserted between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar interbody fusion surgeries. Implants have a central cavity that allows them to be packed with autogenous bone graft and/or allograft bone graft comprised of cancellous and/or corticocancellous bone, and/or demineralized allograft bone with bone marrow aspirate.

Symmetrix™ PX Spinal cages with macro-, micro-, and nano-roughened surface textured features are treated with Titan Surface Technology. Titan nanoLOCK™ Surface Technology is designed to improve fixation to the adjacent bone and provides a microscopic, roughened surface with nano-scale features. Titan nanoLOCK™ Surface Technology is specifically engineered to have nano-textured features at a nanometer (10^{-9}) level which have demonstrated the ability to elicit an endogenous cellular and biochemical response attributed to these nanotextured features *in vitro*. Titan nanoLOCK™ Surface Technology demonstrates the elements to be considered a nanotechnology as outlined in the FDA Nanotechnology Guidance.

Navigation compatibility is managed through the use of previously cleared navigated instrumentation and navigation-enabled workflows. The system is compatible with Medtronic Stealth™ Systems and utilizes existing navigation workflows and instrument tracking capabilities to provide positional guidance during surgery.

V. Indications for Use

Symmetrix™ PX Spinal cages with or without macro-, micro-, and nano-roughened surface textured features are intended to be used at one or two contiguous levels of the lumbar spine (L2-S1) in spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD - defined by discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies), degenerative spondylolisthesis, and/or spinal stenosis. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the levels involved. Additionally, the Symmetrix™ PX Spinal System can be used with patients diagnosed with spinal deformities as an adjunct to fusion. These patients should be skeletally mature and have undergone 6 months of non-operative treatment prior to surgery. Implants are used to facilitate fusion in the lumbar spine using autogenous bone graft and/or allograft bone graft comprised of cancellous and/or corticocancellous bone, and/or demineralized allograft bone with bone marrow aspirate to facilitate fusion. These implants are intended for use with supplemental internal fixation systems.

VI. Comparison of Technological Characteristics with the Predicate Devices

The Symmetrix™ PX Spinal System has the same intended use, principle of operation, material, sterilization and similar design, sizing, manufacturing, and Indications for Use as the identified predicate devices. Based on these comparisons presented in the submission, the Symmetrix™ PX 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." In addition to standard mechanical testing, non-standard axial compression fatigue testing designed to cycle the device through an off-loaded condition was conducted to assess implant performance during expansion and under

physiologically relevant loading conditions representative of clinical use. Results demonstrated mechanical performance that met the acceptance criteria derived from the predicate devices and supported safe and effective operation of the device. MRI safety evaluation was conducted per ASTM F2503, and the implants are labeled MR Conditional.

- Static and fatigue compression per ASTM F2077
- Static and fatigue compression-shear per ASTM F2077
- Push-out force
- Subsidence resistance per ASTM F2267
- MRI safety per ASTM F2503 (MR Conditional)
- Load-Offload Testing (non-standard test)
- Expansion Under Loading Testing (non-standard test)

VIII. Conclusion

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