



July 17, 2026

Medtronic Sofamor Danek USA, Inc.
Michelle Obenauer
Sr. Regulatory Affairs Director
1800 Pyramid Pl.
Memphis, Tennessee 38132

Re: K253011

Trade/Device Name: Catalyft™ PL Expandable Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: July 9, 2026
Received: July 10, 2026

Dear Michelle Obenauer:

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.

K253011

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Please provide the device trade name(s).

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Catalyft PL Expandable Interbody System

Please provide your Indications for Use below.

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The Catalyft PL Expandable Interbody is indicated for use as an intervertebral body fusion device in skeletally mature patients with degenerative disc disease (DDD - defined by discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies) at one or two contiguous levels of the lumbar spine (L2-S1). These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. Additionally, the Catalyft PL Expandable Interbody 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. These implants are intended for use with supplemental internal fixation systems.

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

☒ Prescription Use ([21 CFR 801 Subpart D](#))

☐ Over-The-Counter Use ([21 CFR 801 Subpart C](#))

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510(k) Summary

MEDTRONIC Catalyft™ PL Expandable Interbody System

July 16, 2026

I. Submitter	Medtronic Sofamor Danek USA, Inc. 1800 Pyramid Place Memphis, Tennessee 38132
Contact Person	Michelle Obenauer Sr. Regulatory Affairs Director Email: michelle.obenauer@medtronic.com
II. Name of Device	Catalyft™ PL Expandable Interbody System
Common Name	Intervertebral fusion device with bone graft, lumbar
Classification Name	Intervertebral body fusion device
Regulation Number	21 CFR 888.3080
Classification	Class II
Product Code	MAX
III. Predicate Device	Catalyft™ PL Expandable Interbody System K021425, S.E. 05/24/2021
IV. Device Description	The Catalyft™ PL Expandable Interbody System is an expandable titanium alloy interbody device consisting of interbodies of various widths, lengths, heights, and lordotic angles to accommodate patient anatomy. 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.
V. Indications for Use	The Catalyft™ PL Expandable Interbody System is indicated for use as an intervertebral body fusion device 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) at one or two contiguous levels of the

	lumbar spine (L2-S1). These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. Additionally, the Catalyft™ PL Expandable Interbody 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. These implants are intended for use with supplemental internal fixation systems.
VI. Comparison of Technological Characteristics with the Predicate Device	The subject Catalyft™ PL Expandable Interbody System has the same intended use, indications for use, materials, design, fundamental technology, and sterilization as the predicate Catalyft™ PL Expandable Interbody System (K021425, S.E. 05/24/2021).
VII. Performance Data	In accordance with the Intervertebral Body Fusion Device – Class II Special Controls Guidance for Industry and FDA Staff, Medtronic has evaluated the subject devices to demonstrate substantial equivalence to the predicate device. Non-standard axial compression fatigue testing designed to cycle the device through an off-loaded condition was conducted to support the proposed labeling changes.
VIII. Conclusion	Based on the supporting evidence provided in this premarket notification, Medtronic believes the subject devices are substantially equivalent to the predicate devices.