October 28, 2024

Medtronic Sofamor Danek USA, Inc.
Rose Merlin Jose
Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K241992
Trade/Device Name: Catalyft™ LS Expandable Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVD
Dated: July 8, 2024
Received: September 12, 2024

Dear Rose Merlin Jose:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241992

Device Name

Catalyft™ LS Expandable Interbody System

Indications for Use *(Describe)*

The Catalyft™ LS Expandable Interbody System device, including those with or without micro- and nano-roughened surface textured features, 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). Additionally, the Catalyft™ LS Expandable Interbody System can be used with patients diagnosed with multilevel degenerative scoliosis and sagittal deformities as an adjunct to fusion. 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 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 may be implanted via a variety of open or minimally invasive anterior or oblique approaches.

The Catalyft™ LS Expandable Interbody System device may be used as a stand-alone device or in conjunction with supplemental fixation. When used as a stand-alone device, the Catalyft™ LS Expandable Interbody System device is intended to be used with 4 titanium alloy screws. If the physician chooses to use less than 4 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 20° are intended to be used with 4 screws and supplemental 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.

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510(k) Summary

MEDTRONIC
Catalyft™ LS Expandable Interbody System

Submitter	Medtronic Sofamor Danek, USA Inc. 1800 Pyramid Place Memphis, Tennessee 38132
Contact Person	Rose Merlin Jose Regulatory Affairs Specialist Email: rosemerlin.jose@medtronic.com
Date Prepared	July 8th 2024
Name of Device	Catalyft™ LS Expandable Interbody System
Common Name	Integrated Bone Screws
Classification Name	Intervertebral Body Lumbar Fusion Device with Bone Graft (21 CFR 888.3080)
Classification	Class II
Product Codes	OVD (888.3080)
Predicate Devices	Predicate 1 (Primary Predicate): Catalyft™ LS Expandable Interbody System (K212653, S.E. 11/19/2021) Predicate 2: SOVEREIGN™ Spinal System (K091813, S.E. 11/17/2009) Predicate 3: Crescent™ PEEK (K094025, S.E. 04/26/2010) Predicate 4: Clydesdale™ Spinal System (K132897, S.E. 12/11/2013) Predicate 5: Elevate™ Spinal System (K142559, S.E. 06/09/2015)

Description	The Catalyft™ LS Expandable Interbody System is an expandable titanium alloy interbody device consisting of expandable 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. The interbody devices incorporate Titan Surface Technologies™, where exterior surfaces include nanoLOCK™ surface treatments designed to improve bone fixation to adjacent bone. nanoLOCK™ surface technology provides a microscopic, roughened surface with nano-scale features. nanoLOCK surface technology is specifically engineered to have nano textured features at a nanometer (10-9) level, which has demonstrated the ability to elicit an endogenous cellular and biochemical response attributed to these nanotextured features *in vitro*. nanoLOCK surface technology demonstrates elements to be considered nanotechnology as outlined in the FDA nanotechnology guidance document.
Indications for Use	The Catalyft™ LS Expandable Interbody System device, including those with or without micro- and nano-roughened surface textured features, 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). Additionally, the Catalyft™ LS Expandable Interbody System can be used with patients diagnosed with multilevel degenerative scoliosis and sagittal deformities as an adjunct to fusion. 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 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 may be implanted via a variety of open or minimally invasive anterior or oblique approaches. The Catalyft™ LS Expandable Interbody System device may be used as a stand-alone device or in conjunction with supplemental fixation. When used as a stand-alone device, the Catalyft™ LS Expandable Interbody System device is intended to be used with 4 titanium alloy screws. If the physician chooses to use less than 4 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 20° are intended to be used with 4 screws and supplemental fixation.
Comparison of Technological Characteristics with the Predicate Devices	The subject device has the same fundamental scientific technology, indications for use, lengths, material, and torx drive as the predicate devices (Single Lead Cancellous or Dual lead Cortical/Cancellous thread form). The main technological difference between the subject and predicate devices are the diameters and thread form combination. The subject device and predicates are intended to augment stability during the normal healing process following surgical correction of disorders of the spine.
Performance Data	The subject Catalyft™ LS implants with new subject integrated screws underwent the following mechanical tests to ensure that the main technological differences between the subject and predicate devices do not present a new worst-case: • Static and Dynamic Compression per ASTM F2077-22 • Static and Dynamic Compression Shear per ASTM F2077-22 • Subsidence per ASTM F2267-22 • Expulsion per ASTM F-04.25.02.02 • Wear Debris per ASTM F1877 (2016) • Bone screw push out • MRI Safety Evaluation per ASTM F2503-23, ASTM F2182-19e2, ASTM F2052-21, F2213-17, F2119-07

Conclusion	Based on the supporting evidence provided, Medtronic believes the subject devices are substantially equivalent to the below predicates. Predicate 1 (Primary Predicate): Catalyft™ LS Expandable Interbody System (K212653, S.E. 11/19/2021) Predicate 2: SOVEREIGN™ Spinal System (K091813, S.E. 11/17/2009) Predicate 3: Crescent™ PEEK (K094025, S.E. 04/26/2010) Predicate 4: Clydesdale™ Spinal System (K132897, S.E. 12/11/2013) Predicate 5: Elevate™ Spinal System (K142559, S.E. 06/09/2015)