December 27, 2022

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

Re: K212653
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: MAX, OVD

Dear Madhuvanthi Soundirarajan:

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 19, 2021. Specifically, FDA is updating this SE Letter to correct the product code as an administrative correction.

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 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

November 19, 2021

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

Re: K212653-S001
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: MAX, KWQ, OVD
Dated: November 8, 2021
Received: November 10, 2021

Dear Madhuvanthi Soundirarajan:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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 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

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)*
K212653

Device Name
Catalyft™ LS Expandable Interbody System

Indications for Use *(Describe)*
The Catalyft™ LS 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). 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 approach.
The Catalyft™ LS Expandable interbody system 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 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

August 2021

Submitter	Medtronic Sofamor Danek, USA Inc. 1800 Pyramid Place Memphis, Tennessee 38132 Telephone: (901)396-3133 Fax: (901) 346-9738
Contact Person	Madhuvanthi Soundirarajan Regulatory Affairs Specialist Email: madhuvanthi.soundirarajan@medtronic.com Telephone: (352)-433-9130
Date Prepared	August 2021
Name of Device	Catalyft™ LS Expandable Interbody System
Common Name	Interbody Cages
Classification Name	Intervertebral Body Lumbar Fusion Device with Bone Graft (21 CFR 888.3080)
Classification	Implants: Class II
Product Codes	MAX (888.3080) OVD (888.3080)
Predicate Devices	Predicate 1 (Primary Predicate) – SOVEREIGN™ Spinal System (K172328, S.E 11/02/2017) and (K091813, S.E 11/17/2009). Predicate 2 – BASE Interfixated Titanium (K201820, S.E 09/25/2020) Predicate 3 – CRESCENT™ PEEK (K094025, S.E. 04/26/2010) Predicate 4 – ELEVATE™ Spinal System (K142559, S.E 06/09/2015) Predicate 5- CLYDESDALE™ Spinal System (K132897, S.E 12/11/2013)

	Predicate 6 - CATALYFT ™ PL Expandable Interbody System (K210425, S.E 05/24/21)
Description	The Catalyft™ LS Expandable Interbody system consists of implants, instruments, and trays. The implants are provided sterile and are intended to be surgically implanted between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar intervertebral body fusion. Catalyft™ LS Expandable Interbody System implants are expandable height & lordotic titanium interbody fusion implants. The subject interbody implants have double curved endcaps geometry that will allow the implants to seat inside the vertebral endplate curvature. The interbody implants are made of titanium alloy (Ti-6Al-4V Eli) and they expand for adjustable height and adjustable lordosis. The purpose of the adjustable height and lordosis is to allow the surgeons to have better control and restoration of spinal alignment and lordosis in patients and to appropriately size the interbody to match the patient anatomy.
Indications for Use	The Catalyft™ LS 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). Additionally, the Catalyft™ LS Expandable Interbody System can be used with patients diagnosed with spinal 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 approaches. These approaches include anterior and or oblique approach. The Catalyft™ LS Expandable interbody system cages used with 4 titanium alloy screws may be used as a stand-alone device up to 20°lordosis. 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	Catalyft™ LS Expandable Interbody System has the same fundamental scientific technology, indications for use, design, material, and levels of attachment as the predicate devices. The predicate and the subject devices are intended for stabilization use and to promote bone fusion during the normal healing process following surgical correction of disorders of the spine. The subject interbody implant has a similar expansion mechanism as the Predicate 4 ELEVATE™ Spinal System implant. However, the subject implant has expandable height and lordosis moving both the endcaps during the expansion, whereas the ELEVATE™ implant's bottom endcap remains in fixed position.
Performance Data	The subject Catalyft™ LS implants underwent the following verification tests: • Static and Dynamic Compression per ASTM F2077-18 • Static and Dynamic Compression Shear per ASTM F2077-18 • Subsidence per ASTM F2267-04(2018) • Expulsion per ASTM F-04.25.02.02 • Bone Screw Push Out • MRI Safety Evaluation per ASTM F2052-15, F2213-17, F2219-07, F2182-19e
Conclusion	Based on the supporting evidence provided, Medtronic believes the subject devices are substantially equivalent to the below predicates. • **Predicate 1 (Primary Predicate) – SOVEREIGN™ Spinal System** (K172328, S.E 11/02/2017) **and** (K091813, S.E 11/17/2009). • **Predicate 2 – BASE Interfixated Titanium** (K201820, S.E 09/25/2020) • **Predicate 3 – CRESCENT™ PEEK** (K094025, S.E. 04/26/2010) • **Predicate 4 – ELEVATE™ Spinal System** (K142559, S.E 06/09/2015) • **Predicate 5- CLYDESDALE™ Spinal System** (K132897, S.E 12/11/2013) • **Predicate 6 - CATALYFT ™ PL Expandable Interbody System** (K210425, S.E 05/24/21)