December 16, 2022

Medtronic Sofamor Danek USA, Inc.
Alex Underberg
Senior Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K223153
Trade/Device Name: Catalyft™ LS Expandable Interbody System with Titan nanoLOCK™ Surface Technology
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX, OVD
Dated: October 4, 2022
Received: October 6, 2022

Dear Alex Underberg:

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 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)*

K223153

Device Name

Catalyft™ LS Expandable Interbody System with Titan nanoLOCK™ Surface Technology

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 approach.
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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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# 510(k) Summary

**MEDTRONIC**
**Catalyft™ LS Expandable Interbody System with Titan nanoLOCK™ Surface Technology**

**December 8th, 2022**

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| **Submitter** | Medtronic Sofamor Danek, USA Inc.<br>1800 Pyramid Place<br>Memphis, Tennessee 38132 |
| **Contact Person** | Alex Underberg<br>Senior Regulatory Affairs Specialist<br>Email: alex.r.underberg@medtronic.com<br>Telephone: (901) 344-1443<br>Fax: (901) 346-9738 |
| **Date Prepared** | December 8th, 2022 |
| **Name of Device** | Catalyft™ LS Expandable Interbody System with Titan nanoLOCK™ Surface Technology |
| **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)<br>OVD (888.3080) |
| **Predicate Devices** | Predicate 1 (Primary Predicate): Catalyft™ LS Expandable Interbody System (K212653, S.E. 11/19/2021)<br><br>Predicate 2: Anteralign LS™ Interbody System with Titan nanoLOCK™ Surface Technology (K214010, S.E. 04/12/2022)<br><br>Predicate 3: Crescent™ PEEK (K094025, S.E. 04/26/2010; K133216, S.E. 11/22/2013; K171031, S.E. 07/06/2017)<br><br>Predicate 4: Clydesdale™ Spinal System (K100175, S.E. |

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| | 06/02/2010; K132897, S.E. 12/11/2013; K133577, 09/26/2014)<br><br>Predicate 5: Elevate™ Spinal System (K142559, S.E. 06/09/2015) |
| **Description** | The Catalyft™ LS Expandable Interbody System with Titan nanoLOCK™ Surface Technology consists of new interbody implants that 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.<br><br>The Catalyft™ LS Expandable Interbody System with Titan nanoLOCK™ Surface Technology 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.<br><br>The interbody device is a line extension to add Titan nanoLOCK™ Surface Technology to recently cleared Catalyft™ LS Expandable Interbody System (K212653, S.E. 11/19/2021). The subject interbody incorporates Titan Surface Technologies™, where superior and inferior 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. |

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| **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.<br><br>These implants may be implanted via a variety of open or minimally invasive anterior or oblique approach.<br><br>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 or similar fundamental scientific technology, indications for use, design, material, and levels of attachment as the predicate devices. The subject device and predicates are intended for stabilization use and to promote bone fusion during the normal healing process following surgical correction of disorders of the spine.<br><br>The subject interbody implant has an identical expansion mechanism and size range as that of the primary predicate. |

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| | The only difference between the subject device and the primary predicate device is that the Catalyft™ LS nanoLOCK™ interbody has Titan nanoLOCK™ Surface Technology. |
| **Performance Data** | The subject Catalyft™ LS nanoLOCK™ implants underwent the following verification tests:<br>• Static and Dynamic Compression per ASTM F2077-18<br>• Static and Dynamic Compression Shear per ASTM F2077-18<br>• Subsidence per ASTM F2267-04(2018)<br>• Expulsion testing<br>• Wear Debris per ASTM F1877 (2016)<br>• MRI Safety Evaluation per ASTM 2503-20, ASTM F2182-19e, ASTM 2052-21, F2213-17, F2219-07 |
| **Conclusion** | Based on the supporting evidence provided, Medtronic believes the subject devices are substantially equivalent to the below predicates.<br><br>Predicate 1 (Primary Predicate): Catalyft™ LS Expandable Interbody System (K212653, S.E. 11/19/2021)<br><br>Predicate 2: Anteralign LS™ Interbody System with Titan nanoLOCK™ Surface Technology (K214010, S.E. 04/12/2022)<br><br>Predicate 3: Crescent™ PEEK (K094025, S.E. 04/26/2010; K133216, S.E. 11/22/2013; K171031, S.E. 07/06/2017)<br><br>Predicate 4: Clydesdale™ Spinal System (K100175, S.E. 06/02/2010; K132897, S.E. 12/11/2013; K133577, 09/26/2014)<br><br>Predicate 5: Elevate™ Spinal System (K142559, S.E. 06/09/2015) |