May 24, 2021

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

Re: K210425
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, OLO
Dated: April 23, 2021
Received: April 26, 2021

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 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)*

K210425

Device Name

Catalyft(TM) PL Expandable Interbody System

Indications for Use *(Describe)*

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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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)*

K210425

Device Name

Navigated Instruments Compatible with StealthStation™ System

Indications for Use *(Describe)*

Medtronic Navigated Surgical Instruments are intended to be used during preparation and placement of Medtronic implants during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. Medtronic Navigated Reusable Instruments can be compatible with various Medtronic spinal implant systems.

Navigated surgical instruments are specifically designed for use with the StealthStation™ System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a skull, a long bone, or vertebra, can be identified relative to a CT or MR-based model, fluoroscopy images, or digitized landmarks of the anatomy. An instrument may incorporate a measuring function, which has uses as described on the label and the instruments.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

February 10th, 2021

Submitter	Medtronic Sofamor Danek, USA Inc. 1800 Pyramid Place Memphis, Tennessee 38132 Telephone: (901) 396-3133
Contact Person	Alex Underberg Regulatory Affairs Specialist Telephone: (901) 344-1443 (Direct)
Date Prepared	February 10th, 2021
Name of Device	Catalyft™ PL Expandable Interbody System Medtronic Navigated Manual Reusable Instruments for Use with the StealthStation™ System
Common Name	Interbody Cages; Navigated Instruments
Classification Name	Intervertebral fusion Device with Bone Graft, Lumbar (21 CFR 888.3080); Stereotaxic Instruments (21 CFR 882.4560)
Regulatory Classification	Class II
Product Codes	MAX, OLO
Predicate Devices	Predicate 1 (Primary Predicate): Artic-L™ 3D Ti Spinal System and Artic-XL™ 3D Ti Spinal System (K171689, S.E. 10/05/2017; K190959, S.E. 07/03/2019) Predicate 2: Elevate™ Spinal System (K142559, S.E. 06/09/2015) Predicate 3: Crescent™ Spinal System (K094025, S.E. 04/26/2010; K133216, S.E. 11/22/2013; K171031, S.E. 07/06/2017) Predicate 4: Clydesdale™ Spinal System (K100175, S.E. 06/02/2010; K132897, S.E. 12/11/2013; K133577, 09/26/2014) **Medtronic Navigated Manual Reusable Instruments for Use with StealthStation™ System** Navigated Elevate™ Inserter (K163581, S.E. 04/14/2017)

	Navigated Capstone™ Trials (K131425, S.E. 08/14/2013; K150231, S.E. 06/16/2015) Navigated Disc Prep Instruments (K150231, S.E. 06/16/2015, K163581, S.E. 04/14/2017; K201267, S.E. 08/26/2020)
Description of Devices	The Catalyft™ PL Expandable Interbody System consists of implants, instruments, and cases, trays, and lids. The subject implants are expandable lordotic Titanium Alloy (Ti-6Al-4V ELI) interbody fusion implants that are provided in either an inline straight tip, known as the "PL" implant, or a hockey stick-shaped tip, which is known as the "PL40" implant. The implants are expandable and have varying footprints, heights, and lengths that provide surgeons the ability to have better control of the restoration of lordosis in patients and allows more ability to appropriately size the interbody to match patient anatomy. The subject implants are designed with a hollow center region to house autogenous bone graft and/or allograft bone graft comprised of cancellous and/or corticocancellous bone, and/or demineralized allograft bone with bone marrow aspirate In addition to implants, navigated instruments compatible with the StealthStation™ system have been developed. The subject StealthStation™ System compatible instruments are specific to the subject implants, and there are no changes to the StealthStation™ software related to the stereotaxic instruments in this submission. Previously cleared Navigated Rotating Shavers (K150231, S.E. 06/16/2015, K163581, S.E. 04/14/2017; K201267, S.E. 08/26/2020) will be used as disc prep instruments and trials for the Catalyft™ PL system.

	Cases, trays, and lids have been developed for transportation of the subject instruments.
Indications for Use	**Catalyft™ PL Expandable Interbody System** 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 generation 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. **Medtronic Navigated Manual Reusable Instruments for Use with StealthStation™ System** Medtronic Navigated Surgical Instruments are intended to be used during preparation and placement of Medtronic implants during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. Medtronic Navigated Reusable Instruments can be compatible with various Medtronic spinal implant systems. Navigated surgical instruments are specifically designed for use with the StealthStation™ System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a skull, a long bone, or vertebra, can be

	identified relative to a CT or MR-based model, fluoroscopy images, or digitized landmarks of the anatomy. An instrument may incorporate a measuring function, which has uses as described on the label and the instruments.
Comparison of Technological Characteristics with the Predicate Devices	Catalyft™ PL Expandable Interbody System has the same fundamental scientific technology, indications for use, intended use, design, and material levels of attachment as the predicate devices. The predicate and 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 device has a similar expansion mechanism to that of the predicate Elevate™ Spinal System device. However, the Catalyft™ PL implant's bottom endplate moves during expansion, whereas the Elevate™ implant's bottom endplate remains in a fixed position. Navigated instruments are non-sterile, reusable instruments. The navigated disc prep instruments are existing devices that are not undergoing any design changes. The navigated disc prep instruments are being extended to be used as disc prep instruments and trials for Catalyft™ PL Expandable Interbody System.
Performance Data	Testing on implants was completed in accordance with ASTM 2077 (Compression Fatigue, Compression-Shear Fatigue, Static Compression, and Static Compression-Shear), ASTM 2267 (Subsidence), and ASTM Draft Standard F-04.25.02.02 (Expulsion). Testing was also completed to ensure functionality and compatibility of new/existing instruments. Navigated Instruments underwent verification and validation activities per the Bench Performance Testing section and are compatible to be used with Catalyft™ PL Expandable Interbody System and StealthStation™ System.

Conclusion	Based on the information contained in this submission, Medtronic believes that the subject devices are substantially equivalent to the predicate devices.