December 8, 2021

Medtronic Sofamor Danek USA, INC.
Elizabeth Hamilton
Sr. Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K212524
Trade/Device Name: Anteralign™ Spinal 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, OLO
Dated: November 8, 2021
Received: November 9, 2021

Dear Ms. Hamilton:

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, 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)*
K212524

Device Name
Anteralign™ Spinal System with Titan nanoLOCK™ Surface Technology

Indications for Use *(Describe)*

Anteralign™ Spinal System with Titan nanoLOCK™ Surface Technology System interbody cages with macro-, micro-, and nano- roughened surface textured features are intended to be used in spinal fusion procedures on skeletally mature patients with symptomatic Degenerative Disc Disease (DDD, defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies), degenerative spondylolisthesis, and/or spinal stenosis, at one or two contiguous levels from L2 to S1 whose condition requires the use of interbody fusion. These patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. These patients should have had six months of nonoperative treatment prior to treatment with this device.

Additionally, the Anteralign™ Spinal System with Titan nanoLOCK™ Surface Technology can be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity.

The Anteralign™ Spinal System™ with Titan nanoLOCK™ Surface Technology is intended to be used with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate or a combination thereof. These implants may be implanted via a minimally invasive OLIF or minimally invasive or open DLIF approach. The Anteralign Spinal System must be used with a posterior supplemental internal spinal fixation cleared for use in the lumbar spine.

Miniplate and bone screw components are provided as an option for anti-migration for the lumbosacral levels oblique or lateral above the bifurcation (L2-L5) of the vascular structures. Indications and contraindications of spinal instrumentation systems should be understood by the surgeon.

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)*
K212524

Device Name
Medtronic Navigated Manual Reusable Instruments for Use 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 are 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, 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 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)

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510(k) SUMMARY
MEDTRONIC Sofamor Danek

December 6, 2021

Submitter:	Medtronic Sofamor Danek, USA Inc. 1800 Pyramid Place Memphis, Tennessee 38132 Telephone: (901)399-3395 Fax: (901) 346-9738
Contact Person	Elizabeth Hamilton Sr. Regulatory Affairs Specialist Email : elizabeth.c.hamilton@medtronic.com
Alternate Contact:	Raphael McInnis Sr. Regulatory Affairs Manager Email : raphael.mcinniss@medtronic.com
Date Prepared:	December 6 , 2021
Name of Device	Anteralign™ Spinal System with Titan nanoLOCK™ Surface Technology
Common Name	Interbody Fusion Device. Navigated Instruments
Classification Name	Intervertebral Body Fusion Device with bone graft (21 CFR 888.3080) Spinal Intervertebral Body Fixation Orthosis (21 CFR 888.3060) Stereotaxic Instruments (21 CFR 882.4560)
Regulatory Class	Class II
Product Code	MAX, OVD, OLO
Predicate Devices	**Interbody** Primary Predicate - Endoskeleton™ TL Hyperlordotic Interbody System (K211258, S.E. 05/26/2021) Additional Predicate 2 - Endoskeleton™ TL Interbody System (K211258, S.E. 05/26/2021) Additional Predicate 3 - Adaptix ™ Interbody System with Titan nanoLOCK™ Surface Technology (K201267, SE 07/08/2021) Additional Predicate 4 - Clydesdale ™ Spinal System (K151128, S.E. 08/06/2015; K132897, S.E. 12/11/2013; K133577, S.E. 09/26/2014) Additional Predicate 5 - Capstone™ Spinal System (K073291, S.E. 04/24/08; K123047, S.E. 07/25/13) Additional Predicate 6 – Sovereign™ Spinal System

	(K091813, S.E 11/17/09) Additional Predicate 9 – Artic-XL 3D Ti Spinal System with TIONIC Technology (K190959 – S.E. 7/3/19) **Mini Plates and Screws** Additional Predicate 7- Pivox™ Oblique Lateral Spinal System (K152277, S.E 11/13/15) **Medtronic Navigated Manual Reusable Instruments for Use with StealthStation™ System** Additional Predicate 8- Catalyft™ PL Expandable Interbody System Navigated Trials and Inserter- (K210425, S. E. 5/24/21) Primary Predicate- Endoskeleton™ TL Hyperlordotic Interbody System (K211258, S.E. 05/26/2021)

Description of Device

The Anteralign™ Spinal System with Titan nanoLOCK™ Surface Technology consists of interbody cages, mini plates, bone screws and navigated and non-navigated instruments. The Anteralign™ Spinal System interbody cage, known as Anteralign™ TL, is an additive manufactured titanium cage available in various heights, widths, and lengths with different lordosis options to accommodate patient anatomy. The interbody cages are inserted between two lumbar vertebral bodies to give support and correction during lumbar interbody fusion surgeries. The Anteralign™ TL interbody fusion device is rectangular shaped with a large hollow region in the center to house autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate. The interbody design incorporates honeycomb windows and an open void to allow bone growth through the implant.

The interbody device is treated with Titan Surface Technology, where nanoLOCK™ Surface Technology (MMN) is designed to improve fixation to the adjacent bone. The nanoLOCK™ Surface Technology provides a microscopic-roughened surface with nano-scale features. The nanoLOCK™ Surface Technology is specifically engineered to have nano-textured features at a nanometer (10^{-9}) level, which

have demonstrated the ability to elicit an endogenous cellular and biochemical response attributed to these nanotextured features in vitro. The nanoLOCK™ Surface Technology demonstrates the elements to be considered a nanotechnology as outlined in the FDA nanotechnology guidance.

Anteralign™ TL implants are provided sterile and are intended to be used with supplemental fixation cleared for use in lumbar spine (L2-S1) procedures and may be implanted via a minimally invasive OLIF or minimally invasive or open DLIF approach.

Mini plates and screws are provided as options for anti-migration of the Anteralign™ TL interbody. The miniplate is additively manufactured from titanium powder with a machined-wrought titanium bolt. The miniplate may be positioned either laterally or obliquely and oriented in either cephalad or caudal direction on the Anteralign™ TL cage. The bone screw, which is manufactured from wrought titanium, is then placed through the miniplate intrinsic screw hole. Mini plates and bone screws are offered in various sizes and are provided sterile.

Stainless steel and titanium implants are not compatible. They must not be used together in a construct.

No warranties, express or implied, are made. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded.

The purpose of this Traditional 510(k) submission is to seek clearance for the Anteralign™ Spinal System with Titan nanoLOCK™ Surface Technology devices and demonstrate compatibility of the Anteralign™ Navigated inserter with the Stealth Station™ System S8 Spine Software (K201189, S.E. 05/29/2020).

Indications for Use

Anteralign™ TL Spinal System with Titan nanoLOCK™ Surface Technology System

Anteralign™ Spinal System with Titan nanoLOCK™ Surface Technology System interbody cages with macro-, micro-, and nano- roughened surface textured features are intended to be used in spinal fusion procedures on skeletally mature patients with symptomatic Degenerative Disc Disease (DDD, defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies), degenerative spondylolisthesis, and/or spinal stenosis, at one or two contiguous levels from L2 to S1 whose condition requires the use of interbody fusion. These patients may also have up to Grade 1

Spondylolisthesis or retrolisthesis at the involved levels. These patients should have had six months of nonoperative treatment prior to treatment with this device.

Additionally, the Anteralign™ Spinal System with Titan nanoLOCK™ Surface Technology can be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity.

The Anteralign™ Spinal System™ with Titan nanoLOCK™ Surface Technology is intended to be used with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate or a combination thereof. These implants may be implanted via a minimally invasive OLIF or minimally invasive or open DLIF approach. The Anteralign Spinal System must be used with a posterior supplemental internal spinal fixation cleared for use in the lumbar spine.

Miniplate and bone screw components are provided as an option for anti-migration for the lumbosacral levels oblique or lateral above the bifurcation (L2-L5) of the vascular structures. Indications and contraindications of spinal instrumentation systems should be understood by the surgeon.

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 are 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, 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 described on the label and the instruments.

Comparison of Technological Characteristics with the Predicate Devices

The subject Anteralign™ Spinal System with Titan nanoLOCK™ Surface Technology has the same fundamental scientific technology, intended use, levels of attachment, sterilization method and similar material as the previously cleared predicate devices listed above. Please refer to the substantial equivalence section of this submission for more details.

Performance Data

The subject device Anteralign ™ Spinal System with Titan nanoLOCK™ Surface Technology constructs underwent testing in accordance with the following standards:

- ASTM 2077- Compression Fatigue, Compression Shear Fatigue, Static Compression and Static Compression Shear,
- ASTM 2267- Subsidence
- Expulsion

Navigated Instruments underwent verification and validation activities per the Bench Performance testing Section and are compatible to be used with the Anteralign ™ Spinal system with the Titan nanoLOCK™ Surface Technology.

Conclusion

Based on the information contained in this submission, Medtronic believes that the subject Anteralign™ Spinal System with Titan nanoLOCK™ Surface Technology is substantially equivalent to the following predicates:

- Primary Predicate - Endoskeleton™ TL Hyperlordotic Interbody System (K211258, S.E. 05/26/2021)
- Additional Predicate 2 - Endoskeleton™ TL Interbody System (K211258, S.E. 05/26/2021)
- Additional Predicate 3 - Adaptix ™ Interbody System with Titan nanoLOCK™ Surface Technology (K201267, S.E. 07/08/2021)
- Additional Predicate 4 - Clydesdale ™ Spinal System (K151128, S.E. 08/06/2015; K132897, S.E. 12/11/2013; K133577, 09/26/2014)

- Additional Predicate 5 - Capstone™ Spinal System (K073291, S.E. 04/24/08; K123047, S.E. 07/25/13)
- Additional Predicate 6 - Sovereign™ Spinal System (K091813, S.E 11/17/09)
- Additional Predicate7- Pivox™ Oblique Lateral Spinal System (K152277, S.E 11/13/15)
- Additional Predicate 8- Catalyft PL Expandable Interbody System (K210425, S. E. 5/24/21)
- Additional Predicate 9- Artic-XL 3D Ti Spinal System with TIONIC Technology (K190959 – S.E. 7/3/19)