April 12, 2022

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

Re: K214010
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
Dated: March 14, 2022
Received: March 15, 2022

Dear Elizabeth 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)*
K214010

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.

The Anteralign TL Interbody 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 TL interbody 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
The Anteralign Spinal System with Titan nanoLOCK™ Surface Technology TL interbody may be implanted via a minimally invasive OLIF or minimally invasive or open DLIF approach.

The Anteralign™ LS interbody cage may be used as a stand-alone device or in conjunction with supplemental fixation. The Anteralign LS™ interbody fusion Device may be inserted via minimally invasive or open anterior or oblique approach at one or two contiguous levels from L2 to S1. These approaches include anterior and oblique. When used as a stand-alone device, the Anteralign™ LS cage must be used with 3 screws with devices that have standard lordosis (≤16 degrees). If the physician chooses to use less than 3 screws or none of the provided screws, additional supplemental fixation in the lumbar spine must be used to augment stability. 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. Additionally, cages with lordosis angles greater than 16° are intended to be used with supplemental fixation (e.g. facet screws or posterior 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.

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."

510(k) SUMMARY

MEDTRONIC Sofamor Danek USA, Inc.

Anteralign™ LS

December 21, 2021

I. Submitter

Medtronic Sofamor Danek, USA Inc.
1800 Pyramid Place
Memphis, Tennessee 38132

Contact: Elizabeth Hamilton
Senior Regulatory Affairs Specialist
Email: elizabeth.c.hamilton@medtronic.com

Date Prepared: December *20*, 2021

II. Subject Device

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

Product Codes: MAX, OVD

Common name: Interbody Cages, Instruments

Classification Name: Intervertebral Body Fusion Device with Bone Graft, Lumbar (21 CFR 888.3080)
Intervertebral Body Fusion with intrinsic screws (21 CFR 888.3080)

Classification: Class II

III. Predicate Devices:

Primary Predicate: Anteralign™ Spinal System with Titan nanoLOCK™ Surface Technology (K212524, S.E. 12/08/2021)

Additional Predicate 2: The Endoskeleton™ TAS Interbody System (K211258, S.E. 05/26/2021)

Additional Predicate 3: The Endoskeleton™ TAS Hyperlordotic with nanoLOCK™ (K211258, S.E. 05/26/2021)

Additional Predicate 4: Artic-XL 3D Ti Spinal System with Tionic Technology (K171689, S.E. 10/05/17)

Additional Predicate 5: Capstone PEEK (K073291, S.E. 04/24/2008, K123027, S.E. 07/25/2013)

Additional Predicate 6: LT Cage™ PEEK Lumbar Tapered Fusion Device (P9700155022, S.E. 09/10/2003)

Additional Predicate 7: Crescent PEEK, (K094025, S.E. 04/26/2010)

Additional Predicate 8: Capstone Spinal System PEEK, (K073291 S.E. 04/28/2013 & K123027, S.E. 07/25/2013)

The predicate devices were not subjected to any Recall.

IV. Description: The Anteralign™ Spinal System with Titan nanoLOCK™ Surface Technology consists of TL and LS interbody cages, mini plates, and bone screws.

Anteralign™ Spinal System TL and LS interbody cages are additive manufactured titanium cages available in various heights, widths, lengths, and lordotic angles to accommodate patient anatomy. The TL cage is rectangular shaped whereas the LS cage is oval shaped. The interbodies are inserted between two lumbar vertebral bodies to give support and correction during lumbar interbody fusion surgeries. The interbodies have a central cavity that allows them to be packed with 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 Anteralign™ Spinal System TL interbody cages are provided sterile and are intended to be used with supplemental fixation cleared for use in lumbar spine (L2-S1).

The TL interbody 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 TL cage. The bone screw, which is manufactured from wrought titanium, is then placed through the miniplate intrinsic screw hole. Miniplates and bone screws are offered in different sizes and are provided sterile. Miniplates are only to be used with the TL interbody.

The Anteralign™ LS interbody cage may be used as a stand-alone device or in conjunction with supplemental fixation. When used as a standalone device, the Anteralign LS interbody cage is intended to be used with three screws and must have standard lordosis (⩽16 degrees). The Anteralign™ LS interbody cage is intended to be used in the lumbar sacral region between L2 and S1 and may be implanted via open or minimally invasive procedures for OLIF 51 or ALIF approaches.

The interbody designs incorporate honeycomb windows and an open void to allow bone growth through the implant.
The interbody device is treated with Titan Surface Technology, where Titan nanoLOCK™ Surface Technology (MMN) is designed to improve fixation to the adjacent bone. The Titan nanoLOCK™ Surface Technology provides a microscopic-roughened surface with nano-scale features. The Titan 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 Titan nanoLOCK™ Surface Technology demonstrates the elements to be considered a Nanotechnology as outlined in the FDA Nanotechnology Guidance.

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

V. **Indications for use**: 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.

The Anteralign TL Interbody 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 TL interbody 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
The Anteralign Spinal System with Titan nanoLOCK™ Surface Technology TL interbody may be implanted via a minimally invasive OLIF or minimally invasive or open DLIF approach.

The Anteralign™ LS interbody cage may be used as a stand-alone device or in conjunction with supplemental fixation. The Anteralign LS™ interbody fusion Device may be inserted via minimally invasive or open anterior or oblique approach at one or two contiguous levels from L2 to S1. These approaches include anterior and oblique. When used as a stand-alone device, the Anteralign™ LS cage is must be used with 3 screws with devices that have standard lordosis (≤16 degrees). If the physician chooses to use less than 3 screws or none of the provided screws, additional supplemental fixation in the lumbar spine must be used to augment stability. 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. Additionally, cages with lordosis angles greater than 16° are intended to be used with supplemental fixation (e.g. facet screws or posterior fixation).

VI. **Comparison of Technological Characteristics with the Predicate Devices**:

The subject Anteralign™ LS implants have the same, and /or similar features as the following predicate devices:

- Primary Predicate)- Anteralign™ Spinal System with Titan nanoLOCK™ Surface Technology (K212524, S.E. 12/8/21) is the primary predicate, because the Anteralign™ LS devices are incorporated into this Spinal System. It serves as a predicate for identical intended use, identical materials, identical sterilization method, identical levels of implantation, identical fundamental scientific technology, identical manufacturing method, and similar indications.
- Additional Predicate 2- The Endoskeleton™ TAS Interbody System (K211258, S.E. 05/26/21) serves as a predicate for identical intended use, identical indications, identical method of sterilization, identical levels of implantation, identical fundamental scientific technology and similar overall design and sizing.
- Additional Predicate 3 –The Endoskeleton™ TAS Hyperlordotic with nanoLOCK™ (K211258, S.E. 05/26/21) serves as a predicate for identical intended use, identical indications, identical method of sterilization, identical levels of implantation, identical fundamental scientific technology and similar overall design and sizing.
- Additional Predicate 4 - Artic-XL 3D Ti Spinal System with Tionic Technology (K171689, S.E. 10/05/17) was chosen as a predicate due to identical intended use, identical materials, identical method of sterilization,

identical surgical approach, identical fundamental technology, similar sizing and similar indications.

- Additional Predicate 5 -Capstone Peek (K073291, S.E 4/24/08, K123027, S.E. 7/25/13) serves as a mechanical test predicate.
- Additional Predicate 6 - LT Cage™ PEEK Lumbar Tapered Fusion Device, P9700155022, S.E 9/10/2003 serves as a mechanical test predicate.
- Additional Predicate 7- Crescent PEEK, (K094025, S.E.4/26/10) serves as a mechanical test predicate.
- Additional Predicate 8- Capstone Spinal System PEEK, (K073291 S.E 4/28/13 & K123027, S.E. 7/25/13) serves as a mechanical test predicate.

Both Subject and Predicate devices are based on the same technological characteristics of providing support and correction by surgically implanting fusion devices between lumbar or lumbosacral vertebral bodies

VII. **Performance Data**: **Mechanical Testing**:

In accordance with, "Guidance for Industry and FDA Staff – Spinal System 510(k)'s", Medtronic has evaluated the subject devices to demonstrate substantial equivalence to the predicate devices. Medtronic completed mechanical testing on the devices according to the following industry standards.

- ASTM F1877
- ASTM F2052

- ASTM F2077
- ASTM F2119
- ASTM F2182
- ASTM F2213
- ASTM F2267
- Expulsion Testing

This evaluation has demonstrated that the subject devices have equivalent mechanical strength in comparison to the predicate devices.

VIII. **Conclusion**: Based on the supporting information provided in this pre-market notification, the subject Anteralign™ LS devices are substantially equivalent to the identified predicates.