August 26, 2020

Medtronic Sofamor Danek
Ms. Diamond Wallace
Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K201267
Trade/Device Name: Adaptix 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, OLO
Dated: July 27, 2020
Received: July 29, 2020

Dear Ms. Wallace:

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.
Acting 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)*
K201267

Device Name
Adaptix™ Interbody System with Titan nanoLOCK™ Surface Technology

Indications for Use *(Describe)*
The Adaptix™ Interbody System with Titan nanoLOCK™ Surface Technology is intended to be used in spinal fusion procedures for patients diagnosed with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2 to S1. DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. The Adaptix™ Interbody System with Titan nanoLOCK™ Surface Technology is intended for use with supplemental fixation systems cleared for use in the lumbar spine.

These patients should be skeletally mature and have had six months of nonoperative treatment. The Adaptix™ Interbody 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. These implants may be implanted via an open or a minimally invasive posterior approach and/or transforaminal approach.

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:

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

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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)*
K201267

Device Name
Navigated Disc Prep Instruments

Indications for Use *(Describe)*
Medtronic Navigated Surgical Instruments are intended to be used during the 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)

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K201267 - 510(k) SUMMARY
MEDTRONIC Sofamor Danek

July 27, 2020

Submitter:	Medtronic Sofamor Danek, USA Inc. 1800 Pyramid Place Memphis, Tennessee 38132 Telephone: (901)396-3133 Fax: (901) 346-9738
Contact Person	Diamond Wallace Regulatory Affairs Specialist Telephone: (901)399-2737 (Direct)
Alternate Contact:	Raphael McInnis Sr. Regulatory Affairs Manager Telephone: (901)399-2057 (Direct)
Date Prepared:	July 27, 2020
Name of Device	Adaptix™ Interbody System with Titan nanoLOCK™ Surface Technology Navigated Disc Prep Instruments including Navigated Rotating Shavers
Common Name	Interbody Fusion Device Stereotaxic Instrument, Navigated Instruments
Classification Name	Intervertebral Body Fusion Device with bone graft (21 CFR 888.3080) Stereotaxic Instrument (21 CFR 882.4560)
Regulatory Class	Class II
Product Code	MAX OLO
Predicate Devices	Predicate 1 (Primary) - CAPSTONE® Spinal System K073291 (S.E. 04/24/2008) & K123027 (S.E. 07/25/2013) Predicate 2 - Endoskeleton® TL Hyperlordotic Interbody Fusion Device K191581/S001 (S.E. 01/08/2020) Predicate 3 - 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 4 - Elevate™ Spinal System K142559 (S.E. 06/09/2015) Predicate 5 - CRESCENT® PEEK Vertebral Body Spacer

	K094025 (S.E. 04/26/2010) Predicate 6 - CLYDESDALE® Spinal System K151128 (S.E. 08/06/2015)

Description of Device

Adaptix™ Interbody System with Titan nanoLOCK™ Surface Technology

The Adaptix™ Interbody System with Titan nanoLOCK™ Surface Technology consist of Additively Manufactured (AM) titanium spacers of various lengths, and heights to accommodate patient. These subject implants can be inserted between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar interbody fusion surgeries.

The subject Adaptix™ Interbody System Fusion devices are available in a variety of lengths and heights for treatment in lumbar interbody fusion procedures. The subject device is designed with a large hollow region in the center to house autograft or allograft bone comprised of cancellous and/or corticocancellous bone and/or demineralized allograft bone with bone marrow aspirate. The design incorporates "honeycomb windows" through the interbody device to permit bone growth through the implant. The new bone formation through the Interbody Device is intended to provide long-term structural support and fusion at the implanted disc space. The Interbody Device incorporates Titan Surface Tecnologies™ including a macro-rough surface on the superior and inferior surfaces of the device along with the is entire device being treated with nanoLOCK™ Surface Technology (MMN™) to improve fixation to the adjacent bone. The nanoLOCK™ Surface Technology (MMN™) provides a microscopic roughened surface with nano-scale features.

The subject device is manufactured from Titanium-6 Aluminum-4 Vanadium Extra Low Interstitial (Ti-6Al-4V ELI) powder in accordance with ASTM F3001: Standard specification for additive manufacturing titanium-6 aluminum-4 vanadium ELI (Extra Low Interstitial) with powder bed fusion.

Navigated Disc Prep Instruments including Navigated Rotating Shavers

The Navigated Disc Prep instruments are non-sterile, reusable surgical instruments that are intended to be used to facilitate a discectomy and placement of implants during spinal surgery procedure. The subject devices are compatible with the subject Adaptix™ Interbody System and existing CAPSTONE® Spinal System and are also compatible with the StealthStation. These devices are offered in non-sterile form and are reusable. These subject devices are manufactured from stainless steel and silicone.

Indications for Use

Adaptix™ Interbody System with Titan nanoLOCK™ Surface Technology

The Adaptix™ Interbody System with Titan nanoLOCK™ Surface Technology is intended to be used in spinal fusion procedures for patients diagnosed with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2 to S1. DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. The Adaptix™ Interbody System with Titan nanoLOCK™ Surface Technology is intended for use with supplemental fixation systems cleared for use in the lumbar spine.

These patients should be skeletally mature and have had six months of nonoperative treatment. The Adaptix™ Interbody System with Titan nanoLOCK™ Surface Technology is intended to be used with autograft bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate. These implants may be implanted via an open or a minimally invasive posterior approach and/or transforaminal approach.

Navigated Disc Prep Instruments including Navigated Rotating Shavers

Medtronic Navigated Surgical Instruments are intended to be used during the 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

Adaptix™ Interbody System with Titan nanoLOCK™ Surface Technology

Adaptix™ Interbody System with Titan nanoLOCK™ Surface Technology has the same fundamental scientific technology, indications for use, intended use, design, material levels of attachment as the predicate devices listed above. 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 following technological differences exist between the subject and primary predicate device:

- The predicate has the tapered nose shape, single lateral hole, and 0° lordosis while the subject device has larger double lateral windows along with the dolphin nose shape and 0° lordosis.
- The subject device is additively manufactured titanium unlike the predicate's subtractive PEEK manufacturing process. However, the subject device is substantially equivalent to the manufacturing process and surface treatment of additional predicates presented.

Navigated Disc Prep Instruments including Navigated Rotating Shavers

There are no changes being made to the subject navigated disc prep instruments, and the subject devices have the same fundamental scientific technology, intended use, and design as the previously cleared device. The only difference is that the navigated disc prep instruments' use is being expanded to facilitate implant size selection for the subject Adaptix implants and the predicate Capstone® Spinal System implants.

Performance Data

Adaptix™ Interbody System with Titan nanoLOCK™ Surface

The subject device Adaptix™ Interbody System with Titan nanoLOCK™ Surface Technology constructs underwent static and dynamic testing in accordance with ASTM F2077-18 and ASTM F2267-04(R18), where testing was performed on the worst-case construct. The worst-case bone screw configurations were additionally tested per ASTM F543-17. Particulate and wear analysis on dynamically loaded specimens was conducted per ASTM F1877-16.

Navigated Disc Prep Instruments including Navigated Rotating Shavers

The subject Navigated Disc Prep Instruments underwent the following testing for use with Adaptix™ Interbody System and existing CAPSTONE® Spinal System:

- Navigation Accuracy Analysis confirmed navigated instrument accuracy in both 2D and 3D space.
- Anatomical Simulated Use confirmed instrument functionality under expected use conditions.
- Navigation Simulated Use confirmed navigation system functionality under expected use conditions.
- CAD Model Evaluation verified that the CAD models are accurately reflected in the application software.

- Implant/Instrument Mating Conditions verified that the instruments can be assembled with the appropriate devices according to their intended use.
- Spine Tools Package Functional Testing verified that the Spine Tools package has met the required interface needs.

Conclusion

Based on the information contained in this submission, Medtronic believes that the subject Adaptix™ Interbody System with Titan nanoLOCK™ Surface Technology and Navigated Disc Prep Instruments are substantially equivalent to the following predicates:

- Predicate 1 (Primary) - CAPSTONE® Spinal System
  K073291 (S.E. 04/24/2008) & K123027 (S.E. 07/25/2013)
- Predicate 2 - Endoskeleton® TL Hyperlordotic Interbody Fusion Device
  K191581/S001 (S.E. 01/08/2020)
- Predicate 3 - 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 4 - Elevate™ Spinal System
  K142559 (S.E. 06/09/2015)
- Predicate 5 - CRESCENT® PEEK Vertebral Body Spacer
  K094025 (S.E. 04/26/2010)
- Predicate 6 - CLYDESDALE® Spinal System
  K151128 (S.E. 08/06/2015)