April 22, 2025

Medtronic Sofamor Danek, USA Inc.
Alicia Goins
International Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K250669
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
Dated: February 26, 2025
Received: March 5, 2025

Dear Alicia Goins:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K250669

Please provide the device trade name(s).

Adaptix™ Interbody System with Titan nanoLOCK™ Surface Technology
(Interbody Fusion Device)

Please provide your Indications for Use below.

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 or a bone void filler cleared for use in intervertebral body fusion to facilitate fusion. These implants may be implanted via an open or a minimally invasive posterior approach and/or transforaminal approach.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

K250669 - 510(k) SUMMARY
MEDTRONIC Sofamor Danek
February 5, 2025

Submitter	Medtronic Sofamor Danek, USA Inc. 1800 Pyramid Place Memphis, Tennessee 38132 Telephone: (901)396-3133 Fax: (901) 346-9738
Contact Person	Alicia Goins Regulatory Affairs Specialist Telephone: (901) 399-2440 (Direct)
Alternate Contact	Michelle Obenauer Sr. Regulatory Affairs Director Telephone: (901) 399-2117 (Direct)
Date Prepared	February 5, 2025
Name of Device	Adaptix™ Interbody System with Titan nanoLOCK™ Surface Technology
Common Name	Interbody Fusion Device
Classification Name	Intervertebral Body Fusion Device with bone graft (21 CFR 888.3080)
Regulatory Class	Class II
Product Code	MAX
Predicate Devices	**Primary Predicate:** Adaptix™ Interbody System with Titan nanoLOCK™ Surface Technology (K201267, SE 08/26/2020) **Additional Predicates:** NuVasive Modulus® TLIF and ALIF (K203714, SE 12/23/2021) J&J Conduit EIT™ Cellular Titanium T/PLIF (K222276, SE 10/15/2022)

Description of Device

The Adaptix™ Interbody System with Titan nanoLOCK™ Surface Technology consists of Additively Manufactured (AM) titanium spacers of various lengths, and heights 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. The open geometry of the implants allows them to be packed 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 *or a bone void filler cleared for use in intervertebral body fusion to facilitate fusion*. The Adaptix™ Interbody System with Titan nanoLOCK™ Surface Technology in intended for use with supplemental fixation systems cleared for use in the lumbar spine.

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 *or a bone void filler cleared for use in intervertebral body fusion to facilitate fusion*. 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 Technologies™ including a macro-rough surface on the superior and inferior surfaces of the device along with the 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.

Indications for Use

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 *or a bone void filler cleared for use in intervertebral body fusion to facilitate fusion*. These implants may be implanted via an open or a minimally invasive posterior approach and/or transforaminal approach.

Comparison of Technological Characteristics with the Predicate Devices

Both the subject device and predicate devices are implants which are intended for use and indicated for intervertebral body fusions in skeletally mature patients. Each intervertebral body fusion device is intended for use in interbody fusions in the treatment of symptomatic degenerative disc diseases (DDD) in the lumbar spine.

The predicate and subject devices are intervertebral body fusion devices that share similar shape, size ranges, internal graft chamber volume, and surgical insertion technique.

Differences among the devices include material (PEEK or titanium) and shape. The subject device was originally cleared for use 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. The subject application provides information to support the use of the subject device with bone void fillers cleared for use in intervertebral body fusion to facilitate fusion.

Performance Data

The subject Adaptix™ Interbody System devices do not require any additional data to support their expanded use with bone void fillers to facilitate intervertebral body fusion. This submission does not contain any new or modified implants since the original 510(k) clearance (K201267, S.E. 08-26-2020). The overall design and dimensions of the subject devices are within the established size range of the predicate devices, ensuring compatibility and consistency in performance. Additionally, the intended use of the subject device remains unchanged from the primary predicate, which is to facilitate intervertebral body fusion.

The inclusion of bone void fillers as an additional graft option does not introduce new safety or effectiveness concerns. Bone void fillers are widely used in spinal fusion procedures and have been demonstrated to be safe and effective promoting bone growth and fusion. Additionally, the language permitting the use of bone void fillers mirrors the indications in the additional predicates which have been previously cleared by the FDA and are substantially equivalent to the subject device. Further, the bone void fillers maintain their own indications for use in intervertebral body fusion when used in conjunction with an interverterbral body fusion device, such as the predicate and subject device. The incorporation of bone void fillers as a graft option to when promoting fusion is consistent with established practices and indications and does not impact the safety or effectiveness profile of the subject devices.

Conclusion

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

- K201267, SE 08/26/2020
- K203714, SE 12/23/2021
- K222276, SE 10/15/2022