September 5, 2024

Nanovis LLC
℅ Karen Warden, Ph.D.
President
BackRoads Consulting Inc.
PO Box 566
Chesterland, Ohio 44026

Re: K241605
Trade/Device Name: Adaptix™ PEEK Interbody System with Nanotechnology; Capstone Control™ PEEK Spinal System with Nanotechnology
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: August 6, 2024
Received: August 6, 2024

Dear Dr. Warden:

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241605

Device Name

Adaptix™ PEEK Interbody System with Nanotechnology;
Capstone Control™ PEEK Spinal System with Nanotechnology

Indications for Use *(Describe)*

The Adaptix™ PEEK Interbody System with Nanotechnology devices and the Capstone Control™ PEEK Spinal System with Nanotechnology devices including those with macro-, micro- and nano-roughened surface textured features are intended for spinal fusion procedures in skeletally mature patients with degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies) at one or two contiguous spinal levels from L2-S1. These patients should have had six months of nonoperative treatment. These patients may have had a previous non-fusion spinal surgery and/or may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved spinal level(s).
Additionally, Adaptix™ PEEK Interbody System with Nanotechnology and the Capstone Control™ PEEK Spinal System with Nanotechnology devices can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis. The Adaptix™ PEEK and the Capstone Control™ PEEK devices are to be used with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft and/or demineralized allograft bone with bone marrow aspirate. These implants are intended for use with supplemental fixation indicated for lumbar spinal fusion procedures and 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.

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510(k) Summary

Date:	3 June 2024
Sponsor:	Nanovis Spine, LLC 5865 East State Rd. 14 Columbia City, Indiana 46725 USA (877) 907-6266 (260) 625-3834
Sponsor Contact:	Brian More, CEO
510(k) Contact:	Karen E. Warden, PhD BackRoads Consulting Inc. PO Box 566 Chesterland, OH 44026 Office: 440.729.8457
Proposed Trade Names:	Adaptix™ PEEK Interbody System with Nanotechnology and Capstone Control™ PEEK Spinal System with Nanotechnology
Common Name:	Lumbar interbody fusion device
Device Classification:	Class II
Classification Name, Regulation Number, Product Code:	Intervertebral fusion device with bone graft, lumbar, 888.3080, MAX
Device Description:	The Adaptix™ PEEK Interbody System with Nanotechnology and Capstone Control™ PEEK Spinal System with Nanotechnology consist of interbody implants designed for restoration of sagittal alignment in the lumbar spine. The upper and lower surfaces of the implant incorporate a three-dimensional titanium scaffold with interconnected pores averaging 523 µm, and pore interconnections averaging 229 µm in diameter. This product demonstrates the requirements for nanotechnology. The surface has been deliberately manipulated to produce nanoscale dimensions which exhibit specific properties. The scaffold of the Adaptix™ PEEK and Capstone Control™ PEEK devices is electrochemically treated to possess a controlled nanotopography composed of nanotube arrays having a pore size diameter between 30-90 nanometers. Calcium and phosphate are incorporated into the nanotube surface. The scaffold with nanotubes assists in securing the implant in the intervertebral space and provides radiographic confirmation of the implant location. The Adaptix™ PEEK and Capstone Control™ PEEK devices are available in a variety of sizes to accommodate the individual anatomic and clinical circumstances of each patient.
Indications for Use:	The Adaptix™ PEEK Interbody System with Nanotechnology devices and the Capstone Control™ PEEK Spinal System with Nanotechnology devices including those with macro-, micro- and nano-roughened surface textured features are intended for spinal fusion procedures in skeletally mature patients with degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies) at one or two contiguous spinal levels from L2-S1. These patients should have had six months of nonoperative treatment. These patients may have had a previous non-fusion spinal surgery and/or may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved spinal level(s). Additionally, Adaptix™ PEEK Interbody System with Nanotechnology and the Capstone Control™ PEEK Spinal System with Nanotechnology devices can

	be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis. The Adaptix™ PEEK and the Capstone Control™ PEEK devices are to be used with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft and/or demineralized allograft bone with bone marrow aspirate. These implants are intended for use with supplemental fixation indicated for lumbar spinal fusion procedures and may be implanted via an open or a minimally invasive posterior approach and/or transforaminal approach.
Materials:	The Adaptix™ PEEK and Capstone Control™ PEEK implants are manufactured from polyetheretherketone (PEEK-OPTIMA® LT1) per ASTM F2026. The integral scaffold (OsteoSync) is manufactured from CP titanium (Grade 2) as described by ASTM F67. Marker pins in these lumbar devices are manufactured from tantalum per ASTM F560.
Primary Predicate:	Nano FortiCore® (Nanovis, LLC – K191822)
Additional Predicate:	Cascadia Interbody System (K2M, Inc. – K172009), Lumbar I/F Cage® (DePuy AcroMed Inc. – P960025), Capstone Control™ Spinal System (Medtronic Sofamor Danek USA, Inc. – K190165), Adaptix™ Interbody System with Titan nanoLOCK Surface Technology (Medtronic Sofamor Danek USA, Inc. – K201267)
Performance Data:	Mechanical testing of the worst case Adaptix™ PEEK and Capstone Control™ PEEK implants included static and dynamic axial compression and static and dynamic compression shear according to ASTM F2077. In addition, subsidence tests according to ASTM F2267 and expulsion tests were performed. The mechanical test results demonstrate that the Adaptix™ PEEK and Capstone Control™ PEEK performance is substantially equivalent to the predicate devices. Additionally, MR Compatibility testing per ASTM F2503 was performed. The results demonstrate that the Adaptix™ PEEK and Capstone Control™ PEEK implants can be safely scanned in an MR system.
Technological Characteristics:	The Adaptix™ PEEK Interbody System with Nanotechnology and Capstone Control™ PEEK Spinal System with Nanotechnology possess the same technological characteristics as one or more of the predicate devices. These include: • basic design (structural column), • material (reinforced polymer) and • sizes (comparable to those offered by the predicates) Therefore the fundamental scientific technology of the Adaptix™ PEEK Interbody System with Nanotechnology and Capstone Control™ PEEK Spinal System with Nanotechnology is the same as previously cleared devices.
Conclusion:	The Adaptix™ PEEK Interbody System with Nanotechnology and Capstone Control™ PEEK Spinal System with Nanotechnology implants possess the same intended use and technological characteristics as the predicate devices. Therefore Adaptix™ PEEK Interbody System with Nanotechnology and Capstone Control™ PEEK Spinal System with Nanotechnology are substantially equivalent for its intended use.