June 2, 2023

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

Re: K230936
Trade/Device Name: Anatomic PEEK™ Cervical Fusion System with Nanotechnology
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: March 31, 2023
Received: April 3, 2023

Dear Karen 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 (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,

Katherine D. Kavlock -S

for
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)*
K230936

Device Name

Anatomic PEEK™ Cervical Fusion System with Nanotechnology

Indications for Use *(Describe)*

Anatomic PEEK™ Cervical Fusion System with Nanotechnology devices including those with macro-, micro-, and nano-roughened surface textured features are indicated for use for anterior cervical interbody fusion in skeletally mature patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2 to T1. These patients should have had at least six weeks of non-operative treatment. The Anatomic PEEK™ device is to be used with supplemental fixation; the hyperlordotic implants ($\geq 10°$) are required to be used with an anterior cervical plate. The Anatomic PEEK™ Cervical Fusion System with Nanotechnology is also required to be used 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, and is to be implanted via an open anterior 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.

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510(k) Summary

Date:	31 May 2023
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 Name:	Anatomic PEEK™ Cervical Fusion System with Nanotechnology
Common Name:	Cervical interbody fusion device
Device Classification:	Class II
Classification Name, Regulation Number, Product Code:	Intervertebral fusion device with bone graft, cervical, 888.3080, ODP
Device Description:	The Anatomic PEEK™ Cervical Fusion System with Nanotechnology consists of implants and instruments for implantation. 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 Anatomic 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 Anatomic PEEK™ devices are available in a variety of sizes to accommodate the individual anatomic and clinical circumstances of each patient.
Indications for Use:	Anatomic PEEK™ Cervical Fusion System with Nanotechnology devices including those with macro-, micro-, and nano-roughened surface textured features are indicated for use for anterior cervical interbody fusion in skeletally mature patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2 to T1. These patients should have had at least six weeks of non-operative treatment. The Anatomic PEEK™ device is to be used with supplemental fixation; the hyperlordotic implants (≥ 10°) are required to be used with an anterior cervical plate. The Anatomic PEEK™ Cervical Fusion System with Nanotechnology is also required to be used 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, and is to be implanted via an open anterior approach.

Materials:	The Anatomic 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. Instruments are manufactured from medical grade stainless steel per ASTM F899 and include silicone handles.
Primary Predicate:	Nano FortiCore® (Nanovis, LLC – K191822)
Additional Predicate:	Cascadia Interbody System (K2M, Inc. – K160125), MC+ (LDR Holding, K091088), Anatomic PEEK™ Cervical Fusion System (Medtronic Sofamor Danek USA, Inc. – K192502)
Performance Data:	Mechanical testing of the worst case Anatomic PEEK™ implants included static and dynamic axial compression and static and dynamic torsion according to ASTM F2077. In addition, subsidence tests according to ASTM F2267 and expulsion tests were performed. The mechanical test results demonstrate that the Anatomic PEEK™ performance is substantially equivalent to the predicate devices. Additionally, MR Compatibility testing per ASTM F2503 was performed. The results demonstrate that the Anatomic PEEK™ implants can be safely scanned in an MR system.
Technological Characteristics:	The Anatomic PEEK™ Cervical Fusion System with Nanotechnology possesses 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 Anatomic PEEK™ Cervical Fusion System with Nanotechnology is the same as previously cleared devices.
Conclusion:	The Anatomic PEEK™ Cervical Fusion System with Nanotechnology possesses the same intended use and technological characteristics as the predicate devices. Therefore the Anatomic PEEK™ Cervical Fusion System with Nanotechnology is substantially equivalent for its intended use.