October 11, 2019

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

Re: K191822
Trade/Device Name: Nano FortiCore®, FortiCore®
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP, MAX
Dated: September 18, 2019
Received: September 20, 2019

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,

for
Ronald P. Jean, Ph.D.
Director (Acting)
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191822

Device Name
FortiCore®

Indications for Use *(Describe)*

FortiCore® cervical devices are intended for anterior cervical spinal fusion procedures in skeletally mature patients for the treatment of 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-T1. These patients should have had at least six weeks of nonoperative treatment. FortiCore® cervical devices are to be used with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion and in combination with supplemental fixation indicated for cervical fusion procedures.

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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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K191822

Device Name

Nano FortiCore®

Indications for Use *(Describe)*

Nano FortiCore® cervical devices are intended for anterior cervical spinal fusion procedures in skeletally mature patients for the treatment of 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-T1. These patients should have had at least six weeks of non-operative treatment. Nano FortiCore® cervical devices are to be used with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion and in combination with supplemental fixation indicated for cervical fusion procedures.

Nano FortiCore® lumbar devices 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, Nano FortiCore® lumbar devices can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis. Nano FortiCore® lumbar devices are to be used with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft and with supplemental fixation indicated for lumbar spinal fusion procedures.

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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510(k) Summary

Date:	5 July 2019
Sponsor:	Nanovis, LLC 5865 East State Rd. 14 Columbia City, Indiana 46725 USA (877) 907-6266 (260) 625-3834
Contact:	Matthew Hedrick, CEO & Chief Operating Officer
Trade Names:	FortiCore® and Nano FortiCore®
Common Name:	Interbody fusion device
Device Classification	Class II
Classification Names:	Intervertebral body fusion device with bone graft, cervical & Intervertebral body fusion device with bone graft, lumbar
Regulation, Product Codes:	21 CFR 888.3080, ODP & MAX
Device Description:	FortiCore® and Nano FortiCore® consist 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 Nano FortiCore® devices is electrochemically treated to possess a controlled nanotopography composed of nanotube arrays having an average pore size between 60-80 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 FortiCore® and Nano FortiCore® devices are available in a variety of sizes to accommodate the individual anatomic and clinical circumstances of each patient.
Indications for Use:	FortiCore® cervical devices are intended for anterior cervical spinal fusion procedures in skeletally mature patients for the treatment of 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-T1. These patients should have had at least six weeks of non-operative treatment. FortiCore® cervical devices are to be used with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion and in combination with supplemental fixation indicated for cervical fusion procedures. Nano FortiCore® cervical devices are intended for anterior cervical spinal fusion procedures in skeletally mature patients for the treatment of 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-T1. These patients should have had at least six weeks of non-operative treatment. Nano FortiCore® cervical devices are to be used with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion and in combination with supplemental fixation indicated for cervical fusion procedures. Nano FortiCore® lumbar devices 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, Nano FortiCore® lumbar devices can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis. Nano FortiCore® lumbar devices are to be used with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft and with supplemental fixation indicated for lumbar spinal fusion procedures.
Materials:	FortiCore® and Nano FortiCore® devices are manufactured from PEEK (OPTIMA® LT1, Invibio®) as described by ASTM F2026. The integrated scaffold (BioSync-Ti, Sites Medical) is manufactured from CP titanium as described by ASTM F67. Calcium phosphate is attached to the nanotubes. Marker pins in the lumbar devices are manufactured from tantalum per ASTM F560.
Primary predicate:	FortiCore® (Nanovis LLC, K171312)
Additional predicates:	FortiCore® & Nanovis Interbody (Nanovis LLC, K140280, K160874 & K161485, K110442), ALTA Anterior Cervical Interbody Spacer (Astura Medical, K173324), MC+ (LDR Holding, K091088), Lumbar I/F Cage® (DePuy AcroMed, Inc., P960025)
Performance Data:	Mechanical testing of the worst case FortiCore® and Nano FortiCore® devices was performed according to ASTM F2077 and included static and dynamic compression, static and dynamic compression shear and static and dynamic torsion. In addition, subsidence per ASTM F2267 and expulsion tests were performed. The mechanical test results demonstrate the FortiCore® and Nano FortiCore® device performance is substantially equivalent to the predicate devices. To address the "Points to Consider" in the FDA's *Guidance for Industry: Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology*, in vitro evaluations were performed to quantitate the mineralization of extracellular matrix secreted by osteoblasts and mesenchymal stem cells (MSCs) on surfaces created from a commercially pure titanium substrate. The in vitro study results demonstrated that the surface having Nanovis nanotube arrays develops statistically significantly greater mineralization in both osteoblast and mesenchymal stem cell cultures compared to other surfaces. In addition, bacterial endotoxin testing was conducted in accordance with AAMI ST72:2011 and met the specified testing limit.
Technological Characteristics:	FortiCore® and Nano FortiCore® possess the same technological characteristics as the predicate devices. These include: • performance (as described above), • basic design (hollow structural frame), • implant grade materials (PEEK polymer and titanium), and • sizes (widths, lengths and heights are within the range(s) offered by the predicates). Therefore the fundamental scientific technology of the Nano FortiCore® devices is the same as previously cleared devices.
Conclusion:	FortiCore® and Nano FortiCore® possesses the same intended use and technological characteristics as the predicate devices. Therefore FortiCore® and Nano FortiCore® are substantially equivalent for their intended use.