DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Nanovis, LLC
% Karen E. Warden, Ph.D.
President
Backroads Consulting, Incorporated
P.O. Box 566
Chesterland, Ohio 44026

September 6, 2016

Re: K161485
Trade/Device Name: Nanovis Intervertebral Body Fusion System and Forticore®
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX, OPD
Dated: August 8, 2016
Received: August 10, 2016

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 (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. 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 Parts 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*

K161485

Device Name
Nanovis Intervertebral Body Fusion System

Indications for Use *(Describe)*

When used as a cervical intervertebral body fusion device, the Nanovis Intervertebral Body Fusion System is intended for spinal fusion procedures in skeletally mature patients with degenerative disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) at one spinal level from C2-T1. These patients should have had at least six weeks of non-operative treatment. Nanovis Intervertebral Body Fusion System implants are to be used with autogenous bone graft and in combination with supplemental fixation indicated for cervical fusion procedures.

When used as a lumbar intervertebral body fusion device, the Nanovis Intervertebral Body Fusion System is 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 I spondylolisthesis or retrolisthesis at the involved spinal level(s). Nanovis Intervertebral Body Fusion System implants are to be used with autogenous bone graft and in combination 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*

K161485

Device Name
FortiCore®

Indications for Use *(Describe)*

When used as a cervical intervertebral body fusion device, FortiCore® is intended for spinal fusion procedures in skeletally mature patients with degenerative disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) at one spinal level from C2-T1. These patients should have had at least six weeks of non-operative treatment. FortiCore® devices are to be used with autogenous bone graft and in combination with supplemental fixation indicated for cervical fusion procedures.

When used as a lumbar intervertebral body fusion device, FortiCore® is 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). FortiCore® devices are to be used with autogenous bone graft and in combination 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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FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary

Date:	1 September 2016
Sponsor:	Nanovis Spine, LLC 5865 East State Rd. 14 Columbia City, Indiana 46725 USA (877) 907-6266
Sponsor Contact:	Matthew Hedrick, CEO & Chief Operating Officer
510(k) Contact:	Karen E. Warden, PhD BackRoads Consulting PO Box 566 Chesterland, OH 44026 Office: 440.729.8457
Trade Names:	Nanovis Intervertebral Body Fusion System and FortiCore®
Common Name:	Interbody fusion device
Device Classification	Class II
Classification Name:	Intervertebral body fusion device
Regulation:	888.3080
Device Product Code:	MAX, ODP
Submission Purpose:	To add sizes and modify the external shape of the Nanovis Intervertebral Body Fusion and FortiCore® System PLIF implants, and to provide the Nanovis Intervertebral Body Fusion PLIF implants as sterile packaged.
Device Description:	The Nanovis Intervertebral Body Fusion and FortiCore® Systems include PLIF implants and related instruments for implantation. The upper and lower aspects of the implants from both systems are open and have a central column to be packed with autogenous bone graft. The FortiCore® implants have an integrated titanium scaffold which assists in securing the implant in the intervertebral space. The PLIF devices from both systems are available in a variety of shapes and sizes to accommodate the individual patient anatomy. The Nanovis Intervertebral Body Fusion System and FortiCore® PLIF implants are offered as sterile.
Intended Use:	When used as a cervical intervertebral body fusion device, the Nanovis Intervertebral Body Fusion System is intended for spinal fusion procedures in skeletally mature patients with degenerative disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) at one spinal level from C2-T1. These patients should have had at least six weeks of non-operative treatment. Nanovis Intervertebral Body Fusion System implants are to be used with autogenous bone graft and in combination with supplemental fixation indicated for cervical fusion procedures. When used as a lumbar intervertebral body fusion device, the Nanovis Intervertebral Body Fusion System is 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 I spondylolisthesis or retrolisthesis at the involved spinal level(s). Nanovis Intervertebral Body Fusion System implants are to be used with autogenous bone graft and in combination with supplemental fixation indicated for lumbar spinal fusion procedures.

Intended Use:	When used as a cervical intervertebral body fusion device, FortiCore® is intended for spinal fusion procedures in skeletally mature patients with degenerative disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) at one spinal level from C2-T1. These patients should have had at least six weeks of non-operative treatment. FortiCore® devices are to be used with autogenous bone graft and in combination with supplemental fixation indicated for cervical fusion procedures. When used as a lumbar intervertebral body fusion device, FortiCore® is 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). FortiCore® devices are to be used with autogenous bone graft and in combination with supplemental fixation indicated for lumbar spinal fusion procedures.
Materials:	The Nanovis Intervertebral Body Fusion System implants are available in polyetheretherketone (PEEK- OPTIMA® LT1, Invibio® as described by ASTM F2026) and titanium alloy (Ti-6Al-4V ELI as described by ASTM F136). The PEEK devices incorporate a tantalum marker per ASTM F560. FortiCore® devices are manufactured from polyetheretherketone (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. The FortiCore® devices also incorporate a tantalum marker per ASTM F560.
Primary Predicate:	Nanovis Intervertebral Body Fusion System (Nanovis LLC, K110442)
Additional Predicates:	FortiCore® (Nanovis LLC, K140280) Aleutian® IBF System (K2M, Inc., K133614)
Performance Data:	Static and dynamic compression testing per ASTM F2077 and/or dimensional analyses of the modified Nanovis Intervertebral Body Fusion and FortiCore® devices were performed. The results demonstrated the performance of the modified Nanovis Intervertebral Body Fusion System and modified FortiCore devices are substantially equivalent to the predicate devices. In addition, bacterial endotoxin testing (BET) has been performed. BET as specified in ANSI/AAMI ST-72:2011 confirm an endotoxin limit of 2.15 EU/mL.
Technological Characteristics:	The modified Nanovis Intervertebral Body Fusion System and FortiCore® possess technological characteristics similar to the predicate devices. These include: • performance (as described above), • basic design (hollow structural frame), • implant grade materials (PEEK polymer, tantalum and/or titanium), and • sizes (widths, lengths and heights are within the range(s) offered by the predicates). Therefore the fundamental scientific technology of the FortiCore devices is the similar to previously cleared devices.
Conclusion:	The Nanovis Intervertebral Body Fusion System and FortiCore® possess the same intended use and similar technological characteristics as the predicate devices. Therefore the Nanovis Intervertebral Body Fusion System and FortiCore® are substantially equivalent to legally marketed predicates.