



January 22, 2018

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

Re: K171312
Trade/Device Name: FortiCore®
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: December 11, 2017
Received: December 13, 2017

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. 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); 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.

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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/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
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K171312

Device Name

FortiCore®

Indications for Use (Describe)

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). Additionally, FortiCore® can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis. FortiCore® 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Date:	19 January 2018
Sponsor:	Nanovis, LLC 5865 East State Rd. 14 Columbia City, Indiana 46725 USA (877) 907-6266 (260) 625-3834
Contact Person:	Matthew Hedrick, CEO & Chief Operating Officer
Trade Name:	FortiCore®
Common Name:	Interbody fusion device
Device Classification	Class II
Classification Name:	Intervertebral body fusion device
Regulation:	888.3080
Device Product Code:	MAX
Device Description:	FortiCore® consists of implants and instruments for implantation. The upper and lower aspects of the implant incorporate a three-dimensional titanium scaffold electrochemically treated to possess a controlled nanotopography composed of nanotube arrays with an average pore size between 60-80 nanometers, which assists in securing the implant in the intervertebral space and provides radiographic confirmation of the implant location. Calcium and phosphate are incorporated into the nanotube surface. Nanovis has not submitted data to show that phenomena, including chemical properties or biological effects are attributable to these features. The devices are available in a variety of sizes to accommodate the individual anatomic and clinical circumstances of each patient.
Intended Use:	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). Additionally, FortiCore® can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis. FortiCore® 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® 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.
Primary Predicate:	FortiCore® (Nanovis LLC, K161485)
Additional predicates:	FortiCore® (Nanovis LLC, K140280 & K160874), Lumbar I/F Cage® (DePuy AcroMed, Inc. – P960025), Cascadia Interbody System (K2M, Inc. – K160125).
Performance Data:	Mechanical testing of the worst case FortiCore® devices was performed according to ASTM F2077 and included dynamic compression and static and dynamic compression shear. The mechanical test results demonstrate that the FortiCore device performance is substantially equivalent to the predicate devices.

**Technological
Characteristics:**

FortiCore[®] possesses 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).

Technological characteristics which are different have been supported with descriptive information and/or performance data. Therefore the fundamental scientific technology of the FortiCore[®] devices is the same as previously cleared devices.

Conclusion:

FortiCore[®] possesses the same intended use and technological characteristics as the predicate devices. Therefore FortiCore[®] is substantially equivalent for its intended use.