22 December 2020

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

Re: K203452
Trade/Device Name: Nano FortiFix
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB
Dated: November 20, 2020
Received: November 23, 2020

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 Colin O'Neill, M.B.E.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K203452

Device Name
Nano FortiFix® System

Indications for Use *(Describe)*

The Nano FortiFix® System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the non-cervical spine for the following indications: degenerative disc disease, spinal stenosis, spondylolisthesis, spinal deformities (i.e., scoliosis, kyphosis, and/ or lordosis), trauma (i.e., fracture or dislocation), tumor, pseudarthrosis and/or failed previous fusion. The Nano FortiFix® System can be used in an open approach or a percutaneous approach with MIS instrumentation.

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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Section 7 – 510(k) Summary

Date:	20 November 2020
Sponsor:	Nanovis Spine, LLC 5865 East State Rd. 14 Columbia City, Indiana 46725 USA (877) 907-6266 (260) 625-3834
Sponsor Contact:	Matthew Hedrick, CEO & Chief Operating Officer
510(k) Contact:	Karen E. Warden, PhD BackRoads Consulting Inc. PO Box 566 Chesterland, OH 44026 Office: 440.729.8457
Proposed Trade Name:	Nano FortiFix® System
Common Name:	Posterior spinal system
Device Classification:	Class II
Classification Name:	Thoracolumbosacral pedicle screw system
Regulation:	888.3070
Device Product Code:	NKB
Submission Purpose:	The subject 510(k) adds non-modular polyaxial and monoaxial screws, rods, cross connectors, and set screws to the Nano FortiFix® System.
Device Description:	Nano FortiFix® is a posterior pedicle screw system consisting of rods, polyaxial and monoaxial pedicle screws, connectors and fasteners in a variety of sizes to accommodate differing anatomic requirements. The Nano FortiFix® pedicle screw shaft is available having a nanosurface. The Nano FortiFix® nano pedicle screw has a micro- and nano-roughened surface that demonstrates the requirements for nanotechnology. The surface of the nano screw threads has been deliberately manipulated to produce nanoscale dimensions which exhibit specific properties. These threads are 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.
Indications for Use:	The Nano FortiFix® System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the non-cervical spine for the following indications: DDD (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spinal stenosis, spondylolisthesis, spinal deformities (i.e., scoliosis, kyphosis, and/ or lordosis), trauma (i.e., fracture or dislocation), tumor, pseudarthrosis and/or failed previous fusion. The Nano FortiFix® System can be used in an open approach or a percutaneous approach with MIS instrumentation.
Materials:	Nano FortiFix® System implants are manufactured from titanium alloy as described by ASTM F136. Rods are additionally manufactured from cobalt chrome (ASTM F1537).
Primary Predicate:	Nano FortiFix® System (Nanovis Spine, LLC – K193211)
Additional Predicates:	Nanovis Spinal System (Nanovis LLC – K113173) Altus Spine Pedicle Screw System (Altus Partners, LLC – K181339)

Performance Data:

Mechanical testing of the worst case construct was performed according to ASTM F1717 and included static and dynamic compression and static torsion. The mechanical test results demonstrate that the Nano FortiFix® 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 (OB) and mesenchymal stem cells (MSC) on surfaces created from a titanium alloy substrate. The in vitro study results demonstrated that the Nano FortiFix nanosurface 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:

Nano FortiFix® possesses the same technological characteristics as the predicate devices. These include:

- performance (as described above),
- basic design (rod and screw system),
- implant grade materials (titanium alloy, cobalt chrome), and
- sizes (dimensions are within those offered by the predicates).

Therefore the fundamental scientific technology of the Nano FortiFix® devices is the same as previously cleared devices.

Conclusion:

The Nano FortiFix® System possesses the same intended use and technological characteristics as the predicate devices. Therefore Nano FortiFix® is substantially equivalent for its intended use.