



March 20, 2020

Nanovis Spine LLC  
% Karen E. Warden, Ph.D.  
President  
BackRoads Consulting Inc.  
P.O. Box 566  
Chesterland, Ohio 44026

Re: K193211

Trade/Device Name: Nano FortiFix® System  
Regulation Number: 21 CFR 888.3070  
Regulation Name: Thoracolumbosacral pedicle screw system  
Regulatory Class: Class II  
Product Code: NKB  
Dated: February 18, 2020  
Received: February 19, 2020

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. 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Colin O'Neill, M.B.E.

Assistant 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

## Indications for Use

510(k) Number (if known)  
K193211

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: 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.

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:** 18 February 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

**Trade Name:** Nano FortiFix<sup>®</sup> System

**Common Name:** Posterior spinal system

**Device Classification** Class II

**Classification Name:** Thoracolumbosacral pedicle screw system

**Regulation:** 888.3070

**Device Product Code:** NKB

**Device Description:** Nano FortiFix<sup>®</sup> is a posterior pedicle screw system consisting of rods, polyaxial pedicle screws, connectors and fasteners in a variety of sizes to accommodate differing anatomic requirements. The Nano FortiFix<sup>®</sup> pedicle screw shaft is available with or without a nanosurface. The Nano FortiFix<sup>®</sup> 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<sup>®</sup> 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.

**Materials:** Nano FortiFix<sup>®</sup> System implants are manufactured from titanium alloy as described by ASTM F136. Rods are additionally manufactured from cobalt chrome (ASTM F1537).

**Primary Predicate:** Nanovis Spinal System (Nanovis, LLC – K113173)

**Additional Predicate:** Tiger<sup>®</sup> Spine System (CoreLink LLC – K133369)

**Reference Device:** Nano FortiCore<sup>®</sup> (Nanovis Spine, LLC – K191822)

**Performance Data:** Mechanical testing of the worst case construct was performed according to ASTM F1717 and included static and dynamic compression and static torsion. In addition polyaxial screw tulip/shank pull-off testing was performed on the worst case subconstruct. The mechanical results from these tests demonstrate that the Nano FortiFix<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> devices is the same as previously cleared devices.

**Conclusion:**

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