DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 26, 2016

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

Re: K162250
Trade/Device Name: FortiBridge® Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: October 3, 2016
Received: October 4, 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)*
K162250

Device Name
FortiBridge™ Anterior Cervical Plate System

Indications for Use *(Describe)*

The FortiBridge™ Anterior Cervical Plate System is intended for anterior screw fixation of the cervical spine (C2 to T1). The system is to be used as an adjunct to fusion for the treatment of degenerative disc disease (defined as neck pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fractures or dislocations), tumors, spinal stenosis, deformity (i.e., kyphosis, lordosis or scoliosis), pseudarthrosis 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)

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)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Date:	8 August 2016
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 PO Box 566 Chesterland, OH 44026 Office: 440.729.8457
Trade Name:	FortiBridge® Anterior Cervical Plate System
Common Name:	Anterior cervical plate system
Regulatory Class:	Class II
Classification Name, Regulation, Product Code:	Appliance, fixation, spinal intervertebral body, 888.3060, KWQ
Submission Purpose:	This submission modifies the sterilization and packaging state of the FortiBridge™ Anterior Cervical Plate System implants. These devices will be available as sterile.
Device Description:	The FortiBridge™ System consists of implants and instruments for implantation. It is an anterior cervical plate and screw system which includes fixed and variable screws having standard, self-drilling or self-tapping tips, and one- through four-level plates. The implants are available in a variety of sizes to accommodate the individual anatomic and clinical circumstances of each patient. The devices are sold sterile.
Indications for Use:	The FortiBridge™ Anterior Cervical Plate System is intended for anterior screw fixation of the cervical spine (C2 to T1). The system is to be used as an adjunct to fusion for the treatment of degenerative disc disease (defined as neck pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fractures or dislocations), tumors, spinal stenosis, deformity (i.e., kyphosis, lordosis or scoliosis), pseudarthrosis or failed previous fusion.
Materials:	FortiBridge™ implants are manufactured from titanium alloy as described by ASTM F136.
Primary Predicate:	FortiBridge™ System (Nanovis Spine, LLC – K143706)
Additional Predicate:	MaxAn® Anterior Cervical Plate System (Biomet Spine, LLC – K133518)
Performance Data:	Performance data was not provided in this submission
Technological Characteristics:	The FortiBridge™ System possesses the same technological characteristics as its predicate system. These include: • basic design, • material, • mode of operation and, • anatomic location. Therefore the fundamental scientific technology of the FortiBridge™ System is the same as the previously cleared FortiBridge™ System.

Conclusion: The FortiBridge™ Anterior Cervical Plate System possesses the same indications for use and technological characteristics as the predicate device. Therefore FortiBridge™ Anterior Cervical Plate System is substantially equivalent for its intended use.