December 7, 2017

NuVasive, Inc.
Ms. Olga Lewis
Senior Manager, Regulatory Affairs
7475 Lusk Boulevard
San Diego, California 92121

Re: K173117
Trade/Device Name: NuVasive® VersaTie™ System
Regulation Number: 21 CFR 888.3010
Regulation Name: Bone fixation cerclage
Regulatory Class: Class II
Product Code: OWI
Dated: December 4, 2017
Received: December 6, 2017

Dear Ms. Lewis:

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,

Ronald P. Jean -S for

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173117

Device Name
NuVasive® VersaTie™ System

Indications for Use *(Describe)*
The NuVasive® VersaTie™ System is a temporary implant for use in orthopedic surgery. The System is intended to provide temporary stabilization as a bone anchor during the development of solid bony fusion and aid in the repair of bone fractures.

The indications for use include the following applications:
1. Spinal trauma surgery, used in sublaminar or facet wiring techniques;
2. Spinal reconstructive surgery, incorporated into constructs for the purpose of correction of spinal deformities such as idiopathic and neuromuscular scoliosis in patients 8 years of age or older, adult scoliosis, kyphosis and spondylolisthesis;
3. Spinal degenerative surgery, as an adjunct to spinal fusions.

The VersaTie System may also be used in conjunction with other medical implants made of titanium alloy or cobalt-chromium alloy whenever "wiring" may help secure the attachment of other implants.

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

In accordance with Title 21 of the Code of Federal Regulations, Part 807, and in particular 21 CFR §807.92, the following summary of information is provided:

A. Submitted by:

Olga Lewis
Senior Manager, Regulatory Affairs
NuVasive, Incorporated
7475 Lusk Blvd.
San Diego, California 92121
Telephone: (858) 909-1800

Date Prepared: December 4, 2017

B. Device Name

Trade or Proprietary Name:	NuVasive® VersaTie™ System
Common or Usual Name:	Bone Fixation Cerclage, Sublaminar
Classification Name:	Bone Fixation Cerclage
Device Class:	Class II
Classification:	21 CFR § 888.3010
Product Code:	OWI

C. Predicate Devices

The subject device is substantially equivalent to the primary predicate device NuVasive VersaTie System cleared in K161265.

D. Device Description

The NuVasive VersaTie System is part of a spinal fixation system designed to provide an interface between spinal anatomy and a rod used in spinal surgery. The device is secured around posterior vertebral structures such as the lamina, facet, transverse processes, and spinous process from T1-L5. The system is comprised of braided bands and clamps designed to attach to titanium alloy or cobalt-chromium alloy rods. Implant components are available in a variety sizes and can be rigidly locked into a variety of different configurations to suit the individual pathology and anatomical conditions of the patient. The purpose of this submission is to introduce an additional surgical technique.

E. Intended Use

The NuVasive® VersaTie™ System is a temporary implant for use in orthopedic surgery. The System is intended to provide temporary stabilization as a bone anchor during the development of solid bony fusion and aid in the repair of bone fractures.

The indications for use include the following applications:

1. Spinal trauma surgery, used in sublaminar or facet wiring techniques;
2. Spinal reconstructive surgery, incorporated into constructs for the purpose of correction of spinal deformities such as idiopathic and neuromuscular scoliosis in patients 8 years of age or older, adult scoliosis, kyphosis and spondylolisthesis;
3. Spinal degenerative surgery, as an adjunct to spinal fusions.

The VersaTie System may also be used in conjunction with other medical implants made of titanium alloy or cobalt-chromium alloy whenever "wiring" may help secure the attachment of other implants.

F. Technological Characteristics

As was established in this submission, the subject NuVasive VersaTie System is substantially equivalent to other predicate devices cleared by the FDA for commercial distribution in the United States. The subject device was shown to be substantially equivalent and have equivalent technological characteristics to its predicate device through comparison in areas including design, labeling/intended use, material composition, and function.

G. Performance Data

Nonclinical testing was performed to demonstrate that the subject NuVasive VersaTie System is substantially equivalent to the predicate device. The following testing was performed:

- Static and dynamic Anterior-Posterior band pull-through testing
- Static and dynamic Caudal-Cranial band pull-through testing

The results demonstrate that the subject NuVasive VersaTie System is substantially equivalent to the predicate.

H. Conclusions

The subject NuVasive VersaTie System has been shown to be substantially equivalent to a legally marketed predicate devices for its intended use.