March 21, 2019

NuVasive, Incorporated
Joseph De La Rosa
Specialist, Regulatory Affairs
7475 Lusk Blvd.
San Diego, California 92121

Re: K190418
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: February 19, 2019
Received: February 21, 2019

Dear Joseph De La Rosa:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Colin O'neill -S for MNM

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)*

K190418

Device Name
NuVasive® VersaTie® System

Indications for Use *(Describe)*

The VersaTie System is a temporary implant for use in orthopaedic 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 and 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 the other implants.

Type of Use *(Select one or both, as applicable)*

[X] 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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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:

Joseph De La Rosa
Specialist, Regulatory Affairs
NuVasive, Incorporated
7475 Lusk Blvd.
San Diego, California 92121
Telephone: (858) 309-3744

Date Prepared: March 21, 2019

B. Device Name

Trade or Proprietary Name:	*NuVasive® VersaTie® System*
Common Name:	Bone Fixation Cerclage, Sublaminar
Classification Name:	Bone Fixation Cerclage
Regulation Number:	21 CFR § 888.3010
Product Code:	OWI

C. Predicate Devices

The subject device is substantially equivalent to the primary predicate device NuVasive VersaTie System (K173117). NuVasive Sterile MLX and APX Interbody Devices (K151374) was used as a reference device.

D. Device Description

The *VersaTie System* is part of a spinal posterior 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, and transverse processes from T1-L5. The system is comprised of braided bands, clamps and set screws designed to attach to titanium alloy or cobalt-chromium alloy rods. The purpose of this submission is to introduce design modifications to previously cleared components and add new sterilization method for the clamp component to previously cleared *VersaTie System*.

E. Indications for Use

The VersaTie System is a temporary implant for use in orthopaedic 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 and 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 the 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

Gamma sterilization validation, sterile packaging validation, integrity of the sterile barrier over time validation are performed to qualify new packaging and sterilization method for the *VersaTie System*.

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 legally marketed predicate devices for its intended use.