November 28, 2018

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

Re: K180498
Trade/Device Name: High V+ Bone Cement, NuVasive® Reline® Fenestrated Screws
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: Class II
Product Code: PML, NKB, KWP
Dated: October 25, 2018
Received: October 26, 2018

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. 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,

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)*
K180498

Device Name
NuVasive® Reline® Fenestrated Screws with High V+ Bone Cement

Indications for Use *(Describe)*
NuVasive® Reline® Fenestrated Screws

When used in conjunction with High V+ Bone Cement, the NuVasive Reline Fenestrated Screws are intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion. NuVasive Reline Fenestrated Screws augmented with High V+ Bone Cement are for use at spinal levels where the structural integrity of the spine is not severely compromised.

High V+ Bone Cement

When used in conjunction with the NuVasive Reline Fenestrated Screws, High V+ Bone Cement is intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion. High V+ Bone Cement is limited to use at spinal levels where the structural integrity of the spine is not severely compromised.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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, Medical Affairs
NuVasive, Incorporated
7475 Lusk Blvd.
San Diego, California 92121

Date Prepared: October 25, 2018

B. Device Name

Trade or Proprietary Name:	*NuVasive® Reline® Fenestrated Screws*
Common or Usual Name:	Intervertebral Body Fusion Device
Classification Name:	Pedicle Screw Spinal System, Spinal Interlaminal Fixation Orthosis, Spinal Intervertebral Body Fixation
Device Class:	Class II
Classification:	21 CFR §888.3070
Product Code:	NKB, KWP

Trade or Proprietary Name:	*High V+® Bone Cement*
Common or Usual Name:	Bone cement
Classification Name:	Polymethylmethacrylate (PMMA) bone cement
Device Class:	Class II
Classification:	21 CFR § 888.3027
Product Code:	PML

C. Predicate Devices

The subject *NuVasive Reline Fenestrated Screws* are substantially equivalent to the primary predicate device, the *NuVasive Reline System* (K160989) and the additional predicate device, Medtronic Sofamor Danek USA, Inc., CD HORIZON Fenestrated Screw Set (K152604).

The subject *High V+ Bone Cement* is substantially equivalent to the predicate device, the *Teknimed High V+* (K161114) and the additional predicate device, Medtronic Sofamor Danek USA, Inc., KYPHON HV-R Fenestrated Screw Cement (K152604).

D. Device Description

The *NuVasive Reline Fenestrated Screws* are available in a variety sizes and are designed to connect to 5.0mm, 5.5mm, and 6.0mm diameter rods and associated connecting components contained within the *NuVasive Reline System.* The screws contain fenestrations near the distal tip of the screw which provides a controlled means to deliver a small amount of polymethylmethacrylate (PMMA) bone cement into a targeted vertebral body. These screws are provided sterile or non-sterile.

The *High V+ Bone Cement* is a self-curing PMMA based (high viscosity, radiopaque) bone cement. *High V+ Bone Cement* is provided sterile in two components: 20 grams of powder and 8.6 grams of liquid. The powder contains polymethylmethacrylate, barium sulfate and hydroxyapatite as radiopacifier, and benzoyl peroxide as an initiator. The liquid contains methylmethacrylate monomer, N, N dimethyl-p-toluidine as a promoter and hydroquinone as a stabilizer. The powder and liquid components are mixed, in the provided liquid-to-powder proportions, into a homogenous paste, to initiate the polymerization reaction of monomer into polymer.

The purpose of this 510(k) is to expand the indications for use for the *NuVasive Reline Fenestrated Screws* to include its use with *High V+ Bone Cement* in the treatment of advanced stage tumors of the thoracic and lumbar spine.

E. Intended Use

High V+ Bone Cement:

When used in conjunction with the *NuVasive Reline Fenestrated Screws*, *High V+ Bone Cement* is intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion. *High V+ Bone Cement* is limited to use at spinal levels where the structural integrity of the spine is not severely compromised.

NuVasive Reline Fenestrated Screws:

When used in conjunction with *High V+Bone Cement*, the *NuVasive Reline Fenestrated Screws* are intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion. *NuVasive Reline Fenestrated Screws* augmented with *High V+Bone Cement* are for use at spinal levels where the structural integrity of the spine is not severely compromised.

F. Technological Characteristics

As was established in this submission, the subject *High V+ Bone Cement* is identical in composition, method of manufacture and sterilization to the primary predicate *Teknimed High V+* cleared by FDA in K161114. In addition, the subject *High V+ Bone Cement* is substantially equivalent to the predicate *Medtronic Sofamor Danek USA, Inc., KYPHON HV-R Fenestrated Screw Cement* cleared by the FDA in K152604 for use with *CD HORIZON Fenestrated Screws* in the treatment of advanced stage tumors involving the thoracic and lumbar spine.

As was established in this submission, the subject *NuVasive Reline Fenestrated Screws* are identical in materials and substantially equivalent in design to the primary predicate *NuVasive Reline System* cleared by FDA in K160989 and are 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

To compare the mechanical properties of the *NuVasive Reline Fenestrated Screws* with *High V+ Bone Cement* and *Medtronic CD Horizon Fenestrated Screw* with *Kyphon HV-R Bone Cement*, axial pull-out and removal torque testing was performed according to ASTM F2193. Additionally, a comparison study of the cement flow and bolus formation of the the subject and predicate device was performed.

The subject devices were found to be substantially equivalent to the predicates. No clinical studies were conducted.

H. Conclusions

Based on the indications for use, technological characteristics, and comparison to predicate devices, the subject *NuVasive Reline Fenestrated Screws* and *High V+ Bone Cement* have been shown to be substantially equivalent to legally marketed predicate devices.