July 29, 2022

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

Re: K172979
Trade/Device Name: NuVasive® Growth Rod Conversion Set
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: PGM

Dear Ms. Lewis:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated November 6, 2017. Specifically, FDA is updating this SE Letter because FDA has better categorize your device technology under regulation number, 21 CFR 888.3070.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Ronald Jean, OHT6: Office of Orthopedic Devices, (301)796-5650, Ronald.Jean@fda.hhs.gov.

Sincerely,

Ronald P. Jean -S

Ronald P. Jean, Ph.D.
Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

November 6, 2017

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

Re: K172979
Trade/Device Name: NuVasive® Growth Rod Conversion Set
Regulatory Class: Unclassified
Product Code: PGM
Dated: September 26, 2017
Received: September 27, 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)*
K172979

Device Name
NuVasive® Growth Rod Conversion Set

Indications for Use *(Describe)*
The NuVasive Growth Rod Conversion Set is indicated in patients with potential for additional spinal growth under 10 years of age who require surgical treatment to obtain and maintain correction of severe, progressive, life threatening, early-onset spinal deformities associated with thoracic insufficiency, including early-onset scoliosis. The growth rod conversion implants may be used with Armada, Reline, or Reline 4.5-5.0 rod constructs ranging in diameter from 4.5mm to 6.35mm. The NuVasive Growth Rod Conversion Set is not intended to be used in conjunction with staples.

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.

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

Date Prepared: October 16, 2017

B. Device Name

Trade or Proprietary Name:	*NuVasive® Growth Rod Conversion Set*
Common or Usual Name:	Growing Rod System
Classification Name:	Unclassified
Product Code:	PGM

C. Predicate Devices

The *NuVasive Growth Rod Conversion Set* is substantially equivalent to the primary predicate device, *CD HORIZON Growth Rod Conversion Set* (K133904), and additional predicate device, *Xia Growth Rod Conversion Set* (K142114), and reference devices, *Reline System* (K143684), and *Reline 4.5-5.0 System* (K170126).

D. Device Description

The *NuVasive Growth Rod Conversion Set* consists of connectors designed to convert a traditional fusion construct into a non-fusion growth enabling construct that can be surgically lengthened on a periodic basis as the patient grows. Implant components are available in a variety sizes and can be rigidly locked into a variety of different rod diameters. The devices are manufactured from biocompatible medical grade titanium alloy.

E. Intended Use

The *NuVasive Growth Rod Conversion Set* is indicated in patients with potential for additional spinal growth under 10 years of age who require surgical treatment to obtain and maintain correction of severe, progressive, life threatening, early-onset spinal deformities associated with thoracic insufficiency, including early-onset scoliosis. The growth rod conversion implants may be used with *Armada*, *Reline*, or *Reline 4.5-5.0* rod constructs ranging in diameter from 4.5mm to 6.35mm. The *NuVasive Growth Rod Conversion Set* is not intended to be used in conjunction with staples.

F. Technological Characteristics

As was established in this submission, the subject *NuVasive Growth Rod Conversion Set* 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

Testing previously performed for *Reline System* (K143684) and *Reline 4.5-5.0 System* (K170126) to support fusion applications included subject devices. Comparison to predicate devices indicated for growth rod conversion was performed. No additional testing was provided to support usage for the non-fusion indication.

H. Conclusions

The subject *NuVasive Growth Rod Conversion Set* has been shown to be substantially equivalent to legally marketed predicate devices for its intended use.