July 29, 2022

NuVasive Specialized Orthopedics, Incorporated
Manthan J. Damani
Senior Regulatory Affairs Specialist
101 Enterprise, Suite 100
Aliso Viejo, California 92656

Re: K171791
Trade/Device Name: MAGEC® System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: PGN

Dear Manthan J. Damani:

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 August 31, 2017. Specifically, FDA is updating this SE Letter because FDA has better categorized 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

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

NuVasive Specialized Orthopedics, Incorporated
Mr. Manthan J. Damani
Senior Regulatory Affairs Specialist
101 Enterprise, Suite 100
Aliso Viejo, California 92656

August 31, 2017

Re: K171791
Trade/Device Name: MAGEC® System
Regulatory Class: Unclassified
Product Code: PGN
Dated: August 15, 2017
Received: August 16, 2017

Dear Mr. Damani:

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.

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 (DICE) 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" (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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) 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,

Katherine D. Kavlock -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171791

Device Name
MAGEC® System

Indications for Use *(Describe)*
The MAGEC® System is intended for skeletally immature patients less than 10 years of age with severe progressive spinal deformities (e.g., Cobb angle of 30 degrees or more; thoracic spine height less than 22 cm) associated with or at risk of Thoracic Insufficiency Syndrome (TIS). TIS is defined as the inability of the thorax to support normal respiration or lung growth.

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:

Manthan J. Damani
Senior Regulatory Affairs Specialist
NuVasive Specialized Orthopedics, Inc.
101 Enterprise, Suite 100
Aliso Viejo, CA 92656
Telephone: (858) 909-1800

Date Prepared: August 29, 2017

B. Device Name

Trade or Proprietary Name:	*MAGEC® System*
Common or Usual Name:	Non Fusion Growing Rod System
Classification Name:	Unclassified
Regulation Number:	N/A (Unclassified)
Product Code:	PGN: Growing Rod System- Magnetic Actuation

C. Predicate Devices

The subject device is substantially equivalent to the primary predicate device MAGEC 2 Spinal Bracing and Distraction System (K150885) and additional predicate devices MAGEC Spinal Bracing and Distraction System (K161751, K160352, and K140178).

D. Device Description

The *MAGEC System* is comprised of a sterile single use spinal rod that can be surgically implanted using appropriate NuVasive® Reline®, Reline® 4.5-5.0 (Reline Small Stature) or Armada® fixation components (i.e. pedicle screws, hooks and/or connectors). The implanted MAGEC Rod is used to brace the spine during growth to minimize the progression of scoliosis. The system includes a non-sterile hand held External Remote Controller (ERC) 1 or 2 that is used periodically after implantation to non-invasively distract the implanted spinal rod. The titanium MAGEC Rod includes an actuator portion that holds a small internal magnet. The magnet in the actuator can be turned non-invasively by use of the ERC, which is electrically powered. The hand held non-invasive ERC is placed over the patient's spine and then manually activated, which causes the implanted magnet to rotate and either distract or retract the rod. Once the physician determines that the implant has achieved its intended use and is no longer required, the implant is explanted. Additional accessories for the MAGEC System include the MAGEC Manual Distractor, MAGEC Rod Template, and the MAGEC Wand Magnet Locator. The MAGEC Manual Distractor is a sterile, single use device, which is used in the operating room to test the MAGEC Rod prior to implantation. The MAGEC Manual Distractor used with the MAGEC System is made of Radel and contains a rare-earth magnet. The MAGEC Rod Template is a sterile, single-use accessory used for intraoperative planning of the surgical procedure. The MAGEC Wand Magnet Locator is a non-sterile device which is used during the distraction procedure to locate the magnet within the MAGEC Rod previously implanted in a patient.

The purpose of this premarket notification is to implement design changes to the MAGEC 2 Rod and to allow for use of *MAGEC System* with the NuVasive Reline 4.5-5.0 System.

E. Indications for Use

The *MAGEC® System* is intended for skeletally immature patients less than 10 years of age with severe progressive spinal deformities (e.g., Cobb angle of 30 degrees or more; thoracic spine height less than 22 cm) associated with or at risk of Thoracic Insufficiency Syndrome (TIS). TIS is defined as the inability of the thorax to support normal respiration or lung growth.

F. Comparison of Technological Characteristics with Predicate Device

As was established in this submission, the subject *MAGEC 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 to its predicate device through comparison in areas including design, materials, labeling/intended use, and function.

G. Performance Data

Nonclinical testing was performed to demonstrate that the subject *MAGEC System* is substantially equivalent to the predicate device. Pyrogen testing was performed on the subject device to ensure it meets the pyrogen limit specifications for sterile implant devices.

The following testing was performed:

Test Description	Applicable Test Standard
Static Compression Bending	ASTM F1717-15: Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model
Static Torsion	
Dynamic Compression Bending	
Pyrogenicity – LAL (Kinetic Turbidimetric Assay Pyrogen Test)	ANSI/ AAMI ST72:2011 – Bacterial Endotoxins – Test Methods, Routine Monitoring, and Alternatives to Batch Testing

The results demonstrate that the subject *MAGEC System* is substantially equivalent to the predicate.

H. Conclusions

The subject *MAGEC System* has been shown to be substantially equivalent to legally marketed predicate devices for their intended use.