July 29, 2022

NuVasive Specialized Orthopedics, Inc.
Ivanna Lopez
Regulatory Affairs Specialist
101 Enterprise, Suite 100
Aliso Viejo, California 92656

Re: K201543
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 Ivanna Lopez:

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 July 30, 2020. 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

July 30, 2020

NuVasive Specialized Orthopedics, Inc.
Ivanna Lopez
Regulatory Affairs Specialist
101 Enterprise, Suite 100
Aliso Viejo, California 92656

Re: K201543
Trade/Device Name: *MAGEC® System*
Regulatory Class: Unclassified
Product Code: PGN
Dated: June 8, 2020
Received: June 9, 2020

Dear Ms. Lopez:

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 and Part 809); 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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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

Colin O'Neill, M.B.E.
Acting Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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)*

K201543

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.

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Office of Chief Information Officer
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"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."

MAGEC® System
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:

Ivanna Lopez
Regulatory Affairs Specialist
NuVasive Specialized Orthopedics, Inc.
101 Enterprise, Suite 100
Aliso Viejo, CA 92656
Telephone: (858) 909-1878

Date Prepared: June 08, 2020

B. Device Name

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

C. Predicate Devices

The subject device is substantially equivalent to the following devices:

Primary Predicate

- K171791 – *MAGEC System*

Additional Predicates

- K150885 – *MAGEC 2 Spinal Bracing And Distraction System*
- K140178 – *MAGEC Spinal Bracing And Distraction System*

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 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 assembly process changes and a design change to the MAGEC Rod cleared in K171791 to address the Field Safety Notice and Product Recall issued on February 13, 2020 for the MAGEC X device (FDA Recall Number Z-1898-2020 and Recall Event ID 85495).

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 the Predicate Device

As was established in this submission, the subject *MAGEC® System* is substantially equivalent to the predicates, *MAGEC System* (K171791), *MAGEC 2 Spinal Bracing and Distraction System* (K150885) and *MAGEC Spinal Bracing And Distraction System* (K140178), which were previously cleared by the FDA for commercial distribution in the United States. The subject device has been shown to be substantially equivalent and have equivalent technological characteristics to the predicates through comparison in areas including design, material composition, 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 devices. The following testing was performed:

Testing Description	Applicable Standard
Static Compression Bending	ASTM F1717: *Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model*
Dynamic Compression Bending	
Static Torsion	
Distraction and Retraction Verification	N/A
Torsional Strength	ASTM F1798: *Standard Guide For Evaluating The Static And Fatigue Properties Of Interconnection Mechanisms And Subassemblies Used In Spinal Arthrodesis Implants*

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

H. Conclusions

The subject device, the *MAGEC® System,* has been shown to be substantially equivalent to the legally marketed predicate devices for its intended use.