February 6, 2024

NuVasive Specialized Orthopedics, Incorporated
Miriam Cervantes
Senior Regulatory Affairs Specialist
101 Enterprise
Suite 100
Aliso Viejo, California 92656

Re: K233593
Trade/Device Name: MAGEC Spinal Bracing and Distraction System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: PGN
Dated: November 8, 2023
Received: November 8, 2023

Dear Miriam Cervantes:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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.
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)*
K233593

Device Name
MAGEC Spinal Bracing and Distraction System

Indications for Use *(Describe)*
The MAGEC Spinal Bracing and Distraction System is indicated for skeletally immature patients with severe progressive spinal deformities (e.g., Cobb angle of 30 degrees or more; thoracic spine height less than 22 cm) secondary to early-onset scoliosis 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.

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MAGEC Spinal Bracing and Distraction 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:

Miriam Cervantes
Senior Regulatory Affairs Specialist
NuVasive Specialized Orthopedics, Inc.
101 Enterprise, Suite 100
Aliso Viejo, CA 92656
Telephone: (909) 229-7836

Date Prepared: November 7, 2023

B. Device Name

Trade or Proprietary Name:	*MAGEC Spinal Bracing and Distraction System*
Common or Usual Name:	Non Fusion Growing Rod System
Classification Name:	Growing Rod System- Magnetic Actuation
Device Class:	Class II
Regulation Number:	21 CFR § 888.3070
Product Code:	PGN

C. Predicate Devices

The subject MAGEC Spinal Bracing and Distraction System is substantially equivalent to the primary predicate *MAGEC® System* (K201543) and additional predicates *MAGEC® Spinal Bracing and Distraction System* (K161751) and *Magec Spinal Bracing And Distraction System* (K140613).

D. Device Description

The subject *MAGEC Spinal Bracing and Distraction System* has an identical design and principle of operation to the predicate design iterations cleared in the predicate *Magec System* (K201543, K161751, K140613). The subject system includes sterile single use MAGEC rods manufactured from Ti-6Al-4V, conforming to ASTM F136, along with various accessories including a sterile Rod Template and Manual Distractor, a non-sterile Wand Magnet Locator, and is compatible with a hand held External Remote Controller (ERC) 1 or 2. The MAGEC rod can be surgically implanted using appropriate NuVasive Reline, Reline 4.5-5.0 (Reline Small Stature or RSS) or Armada fixation components (i.e., pedicle screws, hooks and/or connectors). 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. Periodic distraction of the rod is performed to lengthen the spine and to provide adequate bracing during growth to

minimize the progression of scoliosis. Once the physician determines that the implant has achieved its intended use and is no longer required, the implant is explanted.

The purpose of this premarket notification is to expand the indications for use to include treatment of skeletally immature patients of any age with early onset scoliosis.

E. Indications for Use

The MAGEC Spinal Bracing and Distraction System is indicated for skeletally immature patients with severe progressive spinal deformities (e.g., Cobb angle of 30 degrees or more; thoracic spine height less than 22 cm) secondary to early-onset scoliosis 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. Technological Characteristics

As was established in this submission, the subject MAGEC System is substantially equivalent to its predicate devices 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 predicate through comparison in areas including clinical use, design, material composition, intended use, and function.

The following table describes the summary comparison of technological characteristics of the subject device with the predicate device:

	Subject Device	**Predicate Device (K201543/K161571/K140613)**
Indications for Use	The MAGEC Spinal Bracing and Distraction System is indicated for skeletally immature patients with severe progressive spinal deformities (e.g., Cobb angle of 30 degrees or more; thoracic spine height less than 22 cm) secondary to early-onset scoliosis 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.	The Magec System is indicated 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.

Explanation of <u>differences</u> in Indications for Use	The subject device is indicated for skeletally immature patients of any age with early-onset scoliosis. The purpose of specifying early-onset scoliosis is to explicitly identify the treated condition for patients, surgeons, hospitals, and payers. It is solely to clarify the indications. This does not change the intended patient population or treated conditions.	The predicate device is indicated for use in skeletally immature patients less than 10 years of age.
Summary of the technology similarities to the predicate device	• Principle of Operation: Brace the spine during growth to minimize the progression of scoliosis • Material Composition: Titanium • Design: Magnetic mechanism • Accessories: Magec Manual Distractor, Magec Rod Template, and Magec Wand Magnet Locator	• Principle of Operation: Brace the spine during growth to minimize the progression of scoliosis • Material Composition: Titanium • Design: Magnetic mechanism • Accessories: Magec Manual Distractor, Magec Rod Template, and Magec Wand Magnet Locator
Summary of the technology differences to the predicate device	Identical to predicate	No change in technology

G. Performance Data

The subject *MAGEC System* is identical to the predicate *Magec System* (K201543/K161571/K140613). There have been no design changes introduced as part of this submission. The purpose of this submission is to expand the indications for use of the *MAGEC System* to include treatment of skeletally immature patients of any age with early onset scoliosis.

The following non-clinical testing was previously provided and reviewed by FDA:

- Biocompatibility evaluation per ISO 10993-1, including cytotoxicity per ISO 10993-5, chemical characterization per ISO 10993-18 and toxicological risk assessment per ISO 10993-17
- Wear Debris Testing and Post-Wear Debris Testing Device Analysis

As the subject *MAGEC System* device is identical to the predicate *Magec System* (K201543/K161571/K140613) device in design, material, and manufacturing, there are no new risks related to biocompatibility of the subject device when compared to the predicate.

Additionally, a large retrospective registry study of pediatric early-onset scoliosis patients treated with the subject device was performed. The study population consisted of patient groups:

1. **Group 1**: Age at index MAGEC implantation at less than 10 years (N= 1,080 patients)
2. **Group 2**: Age at index MAGEC implantation at 10 years or greater (N= 172 patients)

All patients were diagnosed to have early-onset scoliosis before 10 years of age. All patients were treated with the MAGEC System. In total, there were 1,252 patients treated with the MAGEC System, including 1,080 patients treated before 10 years of age, and 172 patients who were treated with the MAGEC System at 10 years of age or older. The clinical and radiographic data demonstrates that the MAGEC System device, when used in patients 10 years of age or older, is substantially equivalent to the predicate Magec System device indicated for use in patients younger than 10 years of age. Any potential hazards of the changes introduced as part of this submission have been evaluated and assessed to have risk mitigators, and any relevant information has been addressed in the subject device labeling, after all control measures have been implemented.

Data Source	Registry Study		Literature
Study Group	**Group 1 (Predicate)**	**Group 2 (Subject)**	**Group B (Subject)**
Age at Magec implantation	<10 years	≥10 years	≥10 years
Demographic Information			
N	1,080	172	57
Age, mean (range)	6.9 (1-9)	11.3 (10-16)	11.4 (10.0-18.4)
Clinical Outcomes			
Major curve Cobb angle, Δ, mean	26.5%	25.0%	36.6%
Thoracic height (T1-T12), Δ, mean	15.1%	15.5%	16.4%
Spinal height (T1-S1), Δ mean	15.3%	15.3%	15.4%
Device-related adverse events	35.3%	8.1%	10.5%

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

H. Conclusions

The subject *MAGEC Spinal Bracing and Distraction System* has been shown to be substantially equivalent to the legally marketed predicate device for its intended use.