July 29, 2022

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

Re: K160352
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

Dear Lance Justice:

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 October 21, 2016. 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

October 21, 2016

NuVasive Specialized Orthopedics, Inc.
Mr. Lance Justice
Regulatory Affairs Specialist
101 Enterprise, Suite 100
Aliso Viejo, California 92656

Re: K160352
Trade/Device Name: MAGEC® Spinal Bracing and Distraction System
Regulatory Class: Unclassified
Product Code: PGN
Dated: September 8, 2016
Received: September 9, 2016

Dear Mr. Justice:

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 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 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 yours,

Mark N. Melkerson -S

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)*
K160352

Device Name
MAGEC® Spinal Bracing and Distraction System

Indications for Use *(Describe)*
The MAGEC® Spinal Bracing and Distraction System is intended for skeletally immature patients less than 10 years of age with severe progressive spinal abnormalities (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.

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510(k) Summary

MAGEC® Spinal Bracing and Distraction System

Premarket Notification Number: K160352

1. **Company:** NuVasive Specialized Orthopedics, Inc.
   101 Enterprise, Suite 100
   Aliso Viejo, CA 92656

   Contact: Lance Justice
   Regulatory Affairs Specialist
   Phone: (949) 544-6540
   Fax: (949) 837-3664

   Date Prepared: September 8, 2016

2. **Proprietary Trade Name:** MAGEC® Spinal Bracing and Distraction System

3. **Common Name:** Non Fusion Growing Rod System

4. **Classification Name:** Unclassified (Product Code PGN, Growing Rod System – Magnetic Actuation)

5. **Product Description:** The MAGEC Spinal Bracing and Distraction System is comprised of a sterile single use spinal rod that can be surgiclly implanted using appropriate Stryker® Xia® 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 or ERC 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 distract the MAGEC 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 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 Wand Magnet Locator is a non-sterile device which is used during the distraction procedure to locate the magnet within the MAGEC rod. The ERC is placed over this location on the child's back.

6. **Indications for Use:** The MAGEC Spinal Bracing and Distraction System is intended for skeletally immature patients less than 10 years of age with severe progressive spinal deformities (e.g., Cobb angle

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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.

7. **Substantial equivalence:** Documentation that includes mechanical test results, design verification and detailed comparison to the predicate device demonstrates that the MAGEC System is substantially equivalent to the following 510(k) cleared device:

    - MAGEC Spinal Bracing and Distraction System (K150885)

Substantial equivalence to the predicate device is based on indications for use, principles of operation, technological characteristics, and pre-clinical testing performed.

The MAGEC System that is the subject of this premarket notification is identical to the predicate device and has the same indications for use. All design and technological characteristics remain the same. The purpose of the premarket notification is only to revise the labeling from MR Unsafe to MR Conditional.

Non-clinical testing on the MAGEC System was performed to evaluate MRI compatibility in 1.5T clinical scanners. Due to the presence of a permanent magnet in the device, the ASTM standards were applied where possible and custom setups were developed and utilized in order to conduct the evaluations. Test samples were provided in the final manufactured condition and were evaluated for magnetically induced displacement force and torque, MR image artifact, radiofrequency induced heating, and design verification. Results of these testing indicated that, in accordance with relevant ASTM standards, MR Conditional labeling is appropriate.

The FDA guidance document *"Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment (12/11/2014)"* was utilized to determine the specific non-clinical tests required to establish the labeling revision from MR Unsafe to MR Conditional:

Test Description	Applicable Test Standard
Magnetically Induced Displacement Force	ASTM F2052
Magnetically Induced Torque	ASTM F2213
MR Image Artifact	ASTM F2119
Radiofrequency Induced Heating	ASTM F2182
Design Verification	None

Additional non-clinical tests that were performed on the predicate MAGEC System are also applicable to the subject MAGEC System with the MR Conditional labeling change. There are no changes being made to the ERC, the MAGEC Manual Distractor and the MAGEC Wand Magnet Locator as a result of this submission, therefore all testing that was performed on the predicate MAGEC System for those components are applicable to the MAGEC System subject of this premarket notification.

8. **Clinical Performance Data:**

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Previous clinical performance data for the predicate MAGEC System are applicable to this MAGEC System. The safety and probable benefit of the predicate MAGEC System was evaluated outside the United States in a retrospective clinical study for children who had either a primary or revision spinal bracing procedure using the MAGEC System. In assessing probable benefit, the endpoints chosen in the study included Cobb angle correction in the coronal plane, thoracic spine height increase, improvement in space available for lung (SAL), coronal and sagittal balance, reduction in the number of subsequent surgical procedures, and weight gain.

The results of the clinical study showed the MAGEC System provides the benefits of spinal deformity correction and continued growth, similar to that for traditional growing rods, without the need for regular surgical lengthening procedures in these children. As with traditional growing rods, the MAGEC System provides direct bracing to the spine. This bracing provides for correction and maintenance of the scoliotic curve as defined by the Cobb Angle. In addition, a return to a more normal symmetry of the thoracic cavity is provided as demonstrated by the space available for lung (SAL). While implantation of the MAGEC System shares many of the same risks and hazards associated with those of traditional growing rods, the MAGEC System offers the benefit of non-invasive adjustment to lengthen the implanted rod without the need to perform another surgery. The ability of the device to be adjusted non-invasively in length provides the ability of the spine to continue growing in these subjects and for the Thoracic Spine Height to increase with this growth.

9. Conclusion:

Conclusions can be drawn from these tests that the MAGEC System is substantially equivalent to the predicate device.