July 29, 2022

Ellipse Technologies, Incorporated
John McIntyre
Vice President, Regulatory, Quality, and Clinical Affairs
13900 Alton Parkway
Suite 123
Irvine, California 92618

Re: K140178
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 John McIntyre:

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 February 27, 2014. 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

February 27, 2014

Ellipse Technologies, Incorporated
John McIntyre
Vice President, Regulatory, Quality, and Clinical Affairs
13900 Alton Parkway
Suite 123
Irvine, California 92618 US

Re: K140178
Trade/Device Name: MAGEC® Spinal Bracing and Distraction System
Regulation Number: Unclassified
Regulation Name: Unclassified
Regulatory Class: Unclassified
Product Code: PGN
Dated: January 23, 2014
Received: January 24, 2014

Dear Mr. McIntyre:

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Vincent J. Devlin -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 on last page.

510(k) Number *(if known)*
K140178

Device Name
MAGEC® Spinal Bracing and Distraction System

Indications for Use *(Describe)*
The Ellipse 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 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Colin O'Neill

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:

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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."

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510(k) Summary

MAGEC® Spinal Bracing and Distraction System

Premarket Notification Number: K140178

1. **Company:** Ellipse Technologies, Incorporated
   13900 Alton Parkway, Suite 123
   Irvine, CA 92618

   Contact: John McIntyre
   Vice President, RA/QA/CA
   Phone: (949) 837-3600 x203
   Fax: (949) 837-3664

   Date Prepared: February 25, 2014

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. **Predicate Device:** Harrington Rod System, Preamendment

6. **Product Description:** The Ellipse Technologies, Inc. MAGEC Spinal Bracing and Distraction System is comprised of a sterile single use spinal rod that can be surgically implanted using appropriate Stryker® Xia® fixation components (i.e. Pedicle screws, hooks and/or connectors). The system includes a non-sterile hand held External Remote Controller (ERC) that is used at various times after implant to non-invasively lengthen or shorten the implanted spinal rod. The implanted spinal rod is used to brace the spine during growth to minimize the progression of scoliosis. The titanium rod (Ti-6Al-4V ASTM F136) includes an actuator portion

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that holds a small internal magnet. The magnet in the actuator can be turned non-invasively by use of the ERC. Rotation of the magnet causes the MAGEC rod to be lengthened or shorten.

The hand held non-invasive ERC is electrically powered. The ERC is placed over the patient's spine and then manually activated, which causes the implanted magnet to rotate and either lengthen or shorten the rod. Periodic lengthening of the rod is performed to distract 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. Additional accessories for the MAGEC System include the MAGEC Manual Distractor and the MAGEC Wand Magnet Locator. The MAGEC Manual Distractor is a sterilizable, single use device, which is used in the operating room to test the device prior to implantation. 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.

7. **Intended Use:** The Ellipse 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 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.

8. **Substantial equivalence:** Substantial equivalence to the preamendment Harrington Rod System is based on similar indications for use, technological characteristics, and on pre-clinical testing and clinical data.

9. **Technological Characteristics:**

Both the MAGEC System and the predicate are spinal rods that have adjustable length, and are implanted on the posterior spine using hooks or screws. Both systems are manufactured of biocompatible metals and supplied sterile. The difference in the technological characteristics of the predicate device and the MAGEC System is the non-invasive distraction technology, which was previously cleared in Ellipse Orthopedic devices, K101997, K113695, K113219, K131677

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and K133289. This technological difference does not raise new types of issues of safety and effectiveness.

10. Non-Clinical Performance Data:

Non-clinical testing on the MAGEC System included Static and Dynamic Mechanical testing according to the methods outlined in the standard ASTM F1717 and ASTM F2627. Results of these tests demonstrate the MAGEC Spinal Bracing and Distraction System can be expected to perform in a manner substantially equivalent to the predicate devices.

In addition to mechanical testing, design functionality and verification, shelf life testing, validation of the gamma radiation sterilization cycle in accordance with the VD_{max}^{25} methodology as given in ISO 11137-2 to verify that the gamma radiation sterilization process provides a sterility assurance level of 10^{-6}, and biocompatibility in accordance with ISO 10993-1 for the intended use of the device was performed.

The specific non-clinical tests that have been performed in order to establish equivalence to the predicate devices:

Test Description	Applicable Test Standard
Static Mechanical Testing	ASTM F1717
Dynamic Mechanical Testing	ASTM F2624
Shelf Life Packaging Validation	ISO 11607-1
Sterilization of healthcare products – Radiation – Part 2: Establishing the sterilization dose	ANSI/AAMI/ISO 11137-2
Biocompatibility	ISO 10993-1
Device functionality and verification	None
Electrical Safety	IEC 60601-1
Electrical Interference and Compatibility (EMC/EMI)	EN 60601-1-2
Magnetic Field Safety	ICNIRP 2009
Software	FDA "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" Issued May 11, 2005

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In vivo animal studies were performed in the porcine model to evaluate the performance of the MAGEC System and verify that the MAGEC rod is safe and is able to perform per functional specifications. Nine male Yucatan pigs of similar age (mean of 7.2 mo.) were randomly assigned an identifying number and were assigned to one of two test groups designated Group 1 (MAGEC rod) and Group 2 (sham). All animals were of similar weight. Both groups were checked once each week for ten weeks to follow growth progress utilizing Fluoroscopy. For seven weeks post implantation, under sedation, attempted and actual distraction of the Ellipse implantable device (actuator) was recorded in Group 1 using the fluoroscopy images. X-ray and CT were performed post instrumentation implantation (before initial distraction), pre-implant removal, and prior to sacrifice. Results of the in vivo porcine study demonstrates that the MAGEC System is safe and provides an efficient means of non-invasive distraction of the spine. No complications from distraction occurred.

11. Clinical Performance Data:

The safety and probable benefit of the 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 to those of traditional growing rods, the MAGEC System offers the

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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.

12. Conclusion:

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