July 29, 2022

Zimmer Biomet Spine, Inc.
Anthony Maahs
Regulatory Affairs Specialist
10225 Westmoor Drive
Westminster, Colorado 80021

Re: K180227
Trade/Device Name: Polaris Spinal Growth System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: PGM

Dear Anthony Maahs:

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 March 15, 2018. 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

March 15, 2018

Zimmer Biomet Spine, Inc.
Mr. Anthony Maahs
Regulatory Affairs Specialist
10225 Westmoor Drive
Westminster, Colorado 80021

Re: K180227
Trade/Device Name: Polaris Spinal Growth System
Regulatory Class: Unclassified
Product Code: PGM
Dated: January 25, 2018
Received: January 29, 2018

Dear Mr. Maahs:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ronald P. Jean -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180227

Device Name
Polaris Spinal Growth System

Indications for Use *(Describe)*
The Polaris Spinal Growth System is indicated in patients with potential for additional spinal growth under 10 years of age who require surgical treatment to obtain and maintain correction of severe, progressive, life-threatening, early-onset spinal deformities, including early-onset scoliosis, which are associated with or at risk of thoracic insufficiency syndrome.

The Polaris Spinal Growth System may be used with any cleared traditional Polaris Spinal System construct, including any cleared Polaris Spinal System compatibilities.

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."

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR § 807.92.

Preparation Date	March 13, 2018
Applicant/Sponsor	Zimmer Biomet Spine, Inc. 10225 Westmoor Dr. Westminster, CO 80021
Contact Person	Anthony Maahs Regulatory Affairs Specialist Phone: 303-465-8923 Fax: 303-501-8444
Trade Name	Polaris Spinal Growth System
Common Name	Growing Rod System
Device Class	Unclassified
Classification Name	PGM – Growth Rod System
Device Panel	Orthopedic

Device Description & Technological Characteristics:

The Polaris Spinal Growth System is a non-cervical spinal fixation device made from titanium alloy (Ti-6Al-4V) per ASTM F136 and Cobalt Chrome Alloy (Co-28Cr-6Mo) per ASTM F1537. The system is comprised of Growth Connectors which are intended to be used with the Polaris Spinal System implants and instruments. The design and size offerings of the Polaris Spinal Growth System connectors are identical to those currently available in the Polaris Spinal System but are indicated for growth rod constructs. These growth rod constructs typically require repeated planned-lengthening procedures until a determination is made that the patient is ready for a final fusion procedure. After the spine is fused, these devices serve no functional purpose and may be removed.

Intended Use / Indications for Use:

The Polaris Spinal Growth System is indicated in patients with potential for additional spinal growth under 10 years of age who require surgical treatment to obtain and maintain correction of severe, progressive, life-threatening, early-onset spinal deformities, including early-onset scoliosis, which are associated with or at risk of thoracic insufficiency syndrome.

The Polaris Spinal Growth System may be used with any cleared traditional Polaris Spinal System construct, including any cleared Polaris Spinal System compatibilities.

Summary of Technological Characteristics:

The technological characteristics, in regards to design, manufacturing methods, fundamental technology, and operational principles, of the subject Polaris Spinal Growth System components remain identical to those described in their clearance as part of the Polaris Spinal Fixation System (K133746). The purpose of this 510(k) Premarket Notification is to seek clearance for the Polaris Spinal Growth System to be used in pediatric growth application with patients under 10 years of age.

Summary of Performance Data:

To support substantial equivalence, mechanical testing of the Polaris Spinal Growth System constructs were assessed and tested in accordance with ASTM F1717 and ASTM F1798. Performance testing included tests per ASTM F1798 (axial grip strength, torsional grip strength, and flexion/extension moment grip strength) and ASTM F1717 (static compression bending, dynamic compression bending, and static torsion). In all instances, the Polaris Spinal Growth System functioned as intended, meeting the acceptance criteria.

Predicate Devices:

Predicate Device: CD Horizon® Growth Rod Conversion Set (K133904)
Reference Device: Polaris Spinal System (K151974)

Substantial Equivalence Conclusion:

The Polaris Spinal Growth System is substantially equivalent to the predicate systems in regards to intended use, indications for use, fundamental technology including design, materials, manufacturing methods, sterility, and operational principles. The mechanical testing results support this conclusion as they demonstrate that the Polaris Spinal Growth System is able to fulfill its intended use: non-cervical spinal growth and fixation. Based on this information, the subject device does not raise any new issues regarding safety or efficacy when compared to the predicate system.