April 2, 2021

Zimmer Biomet Spine, Inc
Anjanet Mort
Regulatory Affairs Senior Specialist
10225 Westmoor Drive
Westminster, Colorado 80021

Re: K210275
Trade/Device Name: Polaris Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB, KWQ, KWP
Dated: February 22, 2021
Received: March 1, 2021

Dear Anjanet Mort:

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); 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, 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)*

K210275

Device Name
Polaris Spinal System

Indications for Use *(Describe)*

The Polaris Spinal System is a non-cervical spinal fixation device intended for immobilization and stabilization as an adjunct to fusion as a pedicle screw fixation system, a posterior hook and sacral/iliac screw fixation system, or as an anterior or anterolateral fixation system for use with autograft and/or allograft. The Polaris Spinal System is indicated for the following conditions: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma, (i.e., fracture or dislocation), deformity or curvature (i.e., scoliosis, kyphosis, Scheuermann's disease, and/or lordosis,), tumor, stenosis, pseudoarthrosis, or failed previous fusion.

The Ballista and Cypher MIS instruments are intended to be used with Ballista/ Cypher MIS /Polaris 5.5mm implants. Cannulated screws and percutaneous rods may be used with the Ballista/ Cypher MIS instruments to provide the surgeon with a percutaneous approach for posterior spinal surgery for the above indications.

For pediatric patients, the Polaris Spinal System may be used for posterior, non-cervical pedicle screw fixation as an adjunct to fusion to treat adolescent idiopathic scoliosis and is also indicated for treatment of the following conditions: spondylolisthesis/spondylolysis and fractures caused by tumor and/or trauma. Pedicle screw fixation is limited to a posterior approach.

The Polaris Spinal System may be used with the instruments in the AccuVision Minimally Invasive Spinal Exposure System to provide the surgeon with a minimally invasive approach for posterior spinal surgery.

The dominos in the Polaris Spinal System can be used to connect the Polaris Spinal System to the Altius Spinal System, Lineum OCT Spine System, the Array Spinal System, the Biomet Omega21 Spinal System, or the Synergy Spinal System to achieve additional levels of fixation. Please refer to the individual system's Package Insert for a list of the indications for use for each system.

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.

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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	January 29, 2021
Applicant/Sponsor	Zimmer Biomet Spine, Inc. 10225 Westmoor Dr. Westminster, CO 80021
Contact Person	Anjanet Mort Regulatory Affairs Senior Specialist Phone: 720-839-7926 Alex Pawlowski Regulatory Affairs Project Manager Phone: 303-533-1062
Trade Name	Polaris Spinal System
Common Name	Non-cervical spinal fixation system
Device Class	Class II
Product Codes	NKB–Noncervical Pedicle applications KWP–Posterior, noncervical, nonpedicle use KWQ–Anterior/anterolateral noncervical use
Device Panel	Orthopedic
Classification Name	21 CFR 888.3070 Thoracolumbosacral Pedicle Screw System

Device Description & Technological Characteristics:

The Polaris Spinal System is a non-cervical spinal fixation device made from titanium alloy (Ti-6Al-4V) per ASTM F136, unalloyed titanium per ASTM F67, stainless steel per ASTM F138 or ASTM F1314 and Cobalt Chrome Alloy (Co-28Cr-6Mo) per ASTM F1537. The system includes screws, various types and sizes of rods, locking nuts, hooks, lateral connectors, plugs, fixation washers, rod connectors/dominos, various cross connectors and accessories. This submission is to update a contraindication related to the translation screws.

Intended Use / Indications for Use:

The Polaris Spinal System is a non-cervical spinal fixation device intended for immobilization and stabilization as an adjunct to fusion as a pedicle screw fixation system, a posterior hook and sacral/iliac screw fixation system, or as an anterior or anterolateral fixation system for use with autograft and/or allograft. The Polaris Spinal System is indicated for the following conditions: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma, (i.e., fracture or dislocation), deformity or curvature (i.e., scoliosis, kyphosis, Scheuermann's disease, and/or lordosis,), tumor, stenosis, pseudoarthrosis, or failed previous fusion.

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Summary of Technological Characteristics:

The technological characteristics of the subject Polaris Spinal System components remain the same as, or similar to, the Predicate Polaris Spinal System (Primary Predicate - K141804 and Additional Predicates -K140123, K151974) in regards to intended use, indications for use, design, manufacturing methods, fundamental technology, and operational principles. The purpose of this submission is to seek clearance for minor modifications to the labeling related to the translation screw.

Summary of Risk Assessment

No changes were made to any physical component of the Polaris Spinal System. A risk assessment was conducted due to new information from a complaint. That risk assessment led to the inclusion of a contraindication to the labeling. Following the FDA Guidance, Deciding When to Submit a 510(k) for a Change to an Existing Device, a Change Being Effected (CBE) 510k is appropriate when adding a contraindication. Per the FDA Guidance, The Special 510(k) Program, a Special 510(k) is appropriate when it is a change to the manufacturer's own device and performance data is not needed to evaluate the change.

Substantial Equivalence

The subject of the CBE Special 510(k) Polaris Spinal System is substantially equivalent to the Polaris Spinal System (Primary Predicate - K141804 and Additional Predicates -K140123, K151974).

Conclusion:

The Polaris Spinal System is substantially equivalent to the predicate systems as spinal fixation devices in regards to intended use, indications for use, fundamental technology including design, materials, manufacturing methods, sterility, and operational principles. Based on this information, the subject modifications do not raise any new issues regarding the safety or efficacy when compared to its predicates.