



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

Biomet Spine  
Ms. Alexandra Beck  
Regulatory Affairs Specialist  
310 Interlocken Parkway, Suite 120  
Broomfield, Colorado 80021

November 13, 2015

Re: K151974  
Trade/Device Name: Polaris Spinal System  
Regulation Number: 21 CFR 888.3070  
Regulation Name: Pedicle screw spinal system  
Regulatory Class: Class III  
Product Code: NKB, OSH, MNI, MNH, KWP, KWQ  
Dated: October 27, 2015  
Received: October 28, 2015

Dear Ms. Beck:

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 Parts 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

## Indications for Use

510(k) Number (if known)

K151974

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, pseudarthrosis, 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 dominoes 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 510(k) summary is being submitted in accordance with the requirements of 21 CFR § 807.92.

**Preparation Date:** November 12, 2015

**Applicant/Sponsor:** Biomet Spine  
310 Interlocken Parkway, Suite 120  
Broomfield, CO 80021

**Contact Person:** Alexandra Beck  
Regulatory Affairs Specialist  
Phone: 303-501-8397  
Fax: 303-501-8444

**Trade name:** Polaris Spinal System

**Common Name:** Non-cervical spinal fixation system

**Device Class:** Class II & III Pre-amendment

**Classification Name:** Orthosis, Spinal Pedicle Fixation, for Degenerative Disc Disease (NKB)  
Class III pre-amendment device per 21 CFR 888.3070  
Appliance, Fixation, Spinal Interlaminar (KWP)  
Class II per 21 CFR 888.3050  
Appliance, Fixation, Spinal Intervertebral Body (KWQ)  
Class II per 21 CFR 888.3060  
Orthosis, Spondylolisthesis Spinal Fixation (MNH)  
Class II per 21 CFR 888.3070  
Orthosis, Spinal Pedicle Fixation (MNI)  
Class II per 21 CFR 888.3070  
Pedicle Screw Spinal System, Adolescent Idiopathic Scoliosis (OSH)  
Class II per 21 CFR 888.3070

**Device Panel:** Orthopedic

**Primary Predicate:** Polaris Spinal System – K133746

**Reference Device:** Polaris Spinal System – K090203

### **Device Description:**

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. Various instruments are also available for use by the surgeon to facilitate implantation of the device. The purpose of this Premarket Notification is to add modified Ø4.75mm multi-axial screws.

**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/ilic 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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The dominoes 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.

**Summary of Technologies:**

The technological characteristics of the subject Polaris Spinal System components remain the same as, or similar to, the predicate device in regards to intended use, indications for use, design, materials, manufacturing methods, sterility, fundamental technology, and operational principles.

**Performance Data:**

Mechanical testing was conducted in accordance with "FDA's Guidance for Industry and FDA Staff – Spinal System 510(k)s" dated May 3, 2004. Per the guidance document, the following testing was conducted: static compression bending, static torsion and dynamic compression bending fatigue per ASTM F1717, Standard Test Methods for Static and Fatigue for Spinal Implant Constructs in a Vertebrectomy Model and modified flexion-extension testing per ASTM F1798, Standard Guide for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies used in Spinal Arthrodesis Implants. The mechanical testing verifies that the subject components are substantially equivalent to other spinal systems currently on the market for its intended use and has met all mechanical test requirements based on the worst-case construct testing.

**Substantial Equivalence:**

The subject Polaris Spinal System is substantially equivalent to the Polaris Spinal System (K133746).

**Conclusion:**

The Polaris Spinal System is substantially equivalent to the predicate system as a spinal fixation device in regards to intended use, indications for use, fundamental technology including design, materials, manufacturing methods, sterility, and operational principles. Furthermore, mechanical testing and other supporting information sufficiently demonstrate the substantial equivalence of the subject components to the Polaris Spinal System, which has been cleared for a non-cervical spinal fixation. Based on this information, the subject device does not raise any new issues regarding the safety or efficacy when compared to its predicates.