DEC 3 2012

BIOMET SPINE

510(k) Summary
K123451

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

Preparation Date:	November 30, 2012
Applicant/Sponsor:	Biomet Spine 100 Interpace Parkway Parsippany, NJ 07054
Contact Person:	Vivian Kelly Regulatory Affairs Project Manager Phone: 973-299-9300 x2214 Fax: 973-257-0232
Trade name:	Polaris Spinal System –Ballista II Rods
Common Name:	Non-cervical spinal fixation system
Classification Name (Product Code):	Posterior, noncervical, nonpedicle use (KWP) Anterior/anterolateral noncervical use (KWQ) Noncervical pedicle applications (MNI, MNH and NKB)
Device Panel - Regulation No.:	Orthopedic - 21 CFR 888.3050, 888.3060 and 888.3070

Device Description:

The Polaris Spinal System is a non-cervical spinal fixation device. The system includes screws, various types and sizes of rods, locking nuts, hooks, lateral connectors, plugs, fixation washers, rod connectors/dominos and various cross connectors. Various instruments are also available for use by the surgeon to facilitate implantation of the device. This submission is a line extension to Polaris Spinal System to add another style of Ballista rods to the system.

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. Pedicle screw fixation is limited to skeletally mature patients and for use with autograft and/or allograft. The device is indicated for all the following indications: 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, and/or lordosis), tumor, stenosis, pseudoarthrosis, or failed previous fusion.

The Ballista/Ballista II instruments are intended to be used with Ballista/Ballista II /Polaris 5.5mm implants. Cannulated screws and percutaneous rods may be used with the Ballista/Ballista II instruments to provide the surgeon with a percutaneous approach for posterior spinal surgery for the following indications: 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, and/or lordosis), tumor, stenosis, pseudoarthrosis, or failed previous fusion that warrant the

use of a non-cervical spinal fixation device intended for use as a pedicle screw fixation system or sacral/iliac screw fixation system. Pedicle screw fixation is limited to skeletally mature patients and for use with autograft and/or allograft.
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, 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 new components are the same as, or similar to, the predicate devices. The proximal end of the subject device has been modified to remove bulk and to have a dimple and 3 flats instead of the slot and hole design of the predicate device.

Performance Data:
An engineering analysis was conducted to determine if mechanical testing was required for a different style of rod. Because this combination of components did not create a new worst case construct, additional mechanical testing was not required to demonstrate substantial equivalence. Validation testing was conducted to verify that the modified rods can be used with the system's instrumentation.

Substantial Equivalence:

The Ballista II rods in the Polaris Spinal System are substantially equivalent to the other rods in Polaris Spinal System cleared in K121130 and K061441.These new rods are substantially equivalent to the predicate rods with respect to intended use and indications, technological characteristics, and principles of operation and do not present any new issues of safety or effectiveness.

Conclusion:
The subject device is substantially equivalent to its predicates (K121130 & K061441) when used as a spinal fixation device. The indications for use and fundamental technology of the device remain unchanged. Furthermore, validation testing and other supporting information sufficiently demonstrate the substantial equivalence of the subject device to the other components in the Polaris Spinal System. Based on this information, the subject device does not raise any new issues regarding the safety or efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

December 3, 2012

BIOMET Spine (AKA EBI, LLC)
% Ms. Vivian Kelly MS, RAC
Regulatory Affairs Project Manager
100 Interpace Parkway
Parsippany, New Jersey 07054

Re: K123451
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, MNI, MNH, KWP, KWQ
Dated: November 09, 2012
Received: November 09, 2012

Dear Ms. Kelly:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

Erin I. Keith

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123451

Device Name: Polaris Spinal System

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Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ronald P. Jean

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K123451