BIOMET MANUFACTURING CORP.

DEC 11 2013

510(k) SUMMARY

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92

Submitter Information	
Name	Biomet Manufacturing Corp.
Address	56 East Bell Drive Warsaw, IN 46581-0857
Phone number	(574) 267-6639
Fax number	(574) 371-1027
Establishment Registration Number	1825034
Name of contact person	Julie B. Gantenberg, M.S.
Date prepared	September 5, 2013
Name of device	
Trade or proprietary name	Vanguard™ XP Knee System
Common or usual name	Knee Prosthesis
Classification name	Knee joint patellofemorotibial metal/polymer porous- coated uncemented prosthesis (§888.3565) Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis (§888.3560) Knee joint patellofemorotibial semi-constrained UHMWPE pegged uncemented polymer/metal/polymer (§888.3560) Knee joint patellofemorotibial polymer+Additive/metal/polymer +Additive semi-constrained cemented prosthesis (§888.3560)
Classification panel	Orthopedic
Regulation	21CFR §888.3565 21CFR §888.3560
Product Code(s)	JWH, MBH, MBV, OIY
Legally marketed device(s) to which equivalence is claimed	K1222160 Vanguard® XP Knee System (JWH, MBH, MBV, OIY) K113550 Vanguard™ Knee System (JWH, MBH, OIY) K904448 Townley Total Knee (JWH)
Reason for 510(k) submission	Modification of the locking mechanism cleared in K122160 XP System
Device description	The purpose of the submission is to update the locking mechanism cleared in K122160.

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	The Vanguard XP Knee System is a total knee replacement system that consists of a femoral component composed of Co-Cr-Mo, two styles of tibial trays/plates manufactured of Co-Cr-Mo (with locking bar), and dual bearings machined of E1poly. Biomet® patellae can be used with the Vanguard XP Knee System. Both the XP femoral and the XP-CR tibial components are available with a previously cleared porous plasma spray (PPS) coating of titanium alloy and Biomet's Interlok coarse blasted finishes. The Vanguard XP-XP tibial components are available in Biomet's Interlok® coarse blasted finish. Porous coated femoral and tibial components are indicated for cemented and uncemented biological fixation application. Non-coated coarse blasted (Interlok®) femoral and tibial components are indicated for cemented application only. Accessory components are available including removable femoral pegs and femoral augments.
Intended use of the device	The Vanguard™ XP Knee System is intended for replacement of a total knee joint and the preservation of the anterior and/or posterior cruciate ligament (ACL/PCL) when used in conjunction with a femoral, tibial and patellar component.
Indications for use	1. Painful and disabled knee joint resulting from osteoarthritis, rheumatoid arthritis, or traumatic arthritis where one or more compartments are involved. 2. Correction of varus, valgus, or posttraumatic deformity. 3. Correction or revision of unsuccessful osteotomy, arthrodesis, or failure of previous total joint replacement procedure. Femoral components and tibial tray components with porous coatings are indicated for cemented and uncemented biological fixation application. Non-coated (Interlok®) femoral components, tibial tray components and all polyethylene patellar components are indicated for cemented application only. Regenerex components* are intended only for uncemented biologic fixation application. *where available

The Vanguard™ XP Knee System is made up of multiple components, including: instrumentation, femoral components, several types of bearings and tibial trays.

The technological characteristics of the Vanguard™ XP Knee System are the same as those of predicate devices (K122160, K904448, and K113550) in terms of design, material, and principle of operation with the exception of slight modifications as described in this 510(k). The subject locking bar mechanism, tibial and bearing components of the Vanguard™ XP Knee System utilize the identical manufacturing processes as the predicates. The previously cleared, porous plasma spray characterization data on identical substrate was provided in K113550 and used in support of K122160 and subject 510(k). The porous plasma spray coating on the ASTM F75 substrate is for both cemented and uncemented, biologic fixation. Non-clinical testing was conducted to demonstrate that the differences did not adversely affect safety and efficacy, and to demonstrate substantial equivalence to the predicate components. All testing met or exceeded the established acceptance criteria. This information is detailed below in the Performance (Non-clinical) section.

PERFORMANCE DATA

SUMMARY OF NON-CLINICAL TESTS

Performance Test Summary-New Device

The following tests/rationale were performed for the new Vanguard® XP Knee System:

- Tibiofemoral Mechanical Stability / Locking Mechanism Test
- Static Locking Mechanism Test
- Tibial Fixation and Cyclic Locking Mechanism Test
- Cyclic Fatigue of Tibial Tray Test
- Tibial/Bearing Assembly Verification Test
- Locking Bar Insertion and Push-Out Test
- MRI Compatibility Rationale

SUMMARY OF CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE AND/OR OF CLINICAL INFORMATION

Clinical Performance Data/Information: N/A

CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA

No clinical testing was necessary for a determination of substantial equivalence.

The results of mechanical testing indicated the devices performed within the intended use, did not raise any new safety and efficacy issues and were found to be substantially equivalent to the predicate devices.

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

December 11, 2013

Biomet Manufacturing Corporation
Julie B. Gantenberg, M.S.
Senior Regulatory Affairs Specialist
56 East Bell Drive
Warsaw, Indiana 46581

Re: K132873
Trade/Device Name: Vanguard™ XP Knee System
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Codes: MBH, JWH, MBV, OIY
Date: September 5, 2013
Received: September 13, 2013

Dear Ms. Gantenberg:

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" (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 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,

Ronald P. Jean -S for

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): K132873

Device Name: Vanguard™ XP Knee System

Indications For Use:

1. Painful and disabled knee joint resulting from osteoarthritis, rheumatoid arthritis, or traumatic arthritis where one or more compartments are involved.
2. Correction of varus, valgus, or posttraumatic deformity.
3. Correction or revision of unsuccessful osteotomy, arthrodesis, or failure of previous total joint replacement procedure.

Femoral components and tibial tray components with porous coatings are indicated for cemented and uncemented biological fixation application. Non-coated (Interlok®) femoral components, tibial tray components and all polyethylene patellar components are indicated for cemented application only. Regenerex components* are intended only for uncemented biologic fixation application.

*Where Available

Prescription Use ___X___ AND/OR Over-The-Counter Use __NO__
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices