K093293

BIOMET
MANUFACTURING CORP.

OCT 2 2 2010

510(k) Summary

Preparation Date: October 20, 2010

Applicant/Sponsor: Biomet Manufacturing Corp.

Contact Person: Gary Baker

Proprietary Name: Vanguard™ 360 Revision Knee System

Common Name: Knee prostheses

Classification Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis (21 CFR §888.3560)

Product Codes: JWH, MBV

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

Vanguard™ SSK Knee System	K042757	Biomet
Offset Tibial Tray	K010212	Biomet
MCK [Maxim®] Knee System	K915132	Biomet

Device Description: The Vanguard™ 360 Revision Knee System is a series of femoral, tibial and offset adapter components designed to work in conjunction with femoral stems, bearings, trays, augments and patella components of Biomet's previously cleared Maxim® and Vanguard™ SSK knee systems. These components can be used for either primary or revision procedures, but are specifically designed for use where there is inadequate bone stock. Biomet has developed this system in order to expand its product line and update its currently marketed Vanguard™ [SSK] Knee System (K042757).

The Vanguard™ 360 femoral components are made of Co-Cr-Mo alloy and incorporate the same design features as the predicate Vanguard SSK femoral components. The tibial components incorporate the same tibial tray profile as the current Biomet Tibial Trays and the predicate Offset Tibial Tray design and are made of Ti-6Al-4V titanium alloy. The femoral and tibial components are designed for use with the Biomet knee stems cleared in the predicate MCK (Maxim®) System. A series of tibial and femoral augments made of Ti-6Al-4V titanium alloy, allow for the modularity to accommodate bone defects that may be present during revision surgeries. The Ti-6Al-4V titanium alloy Offset Adapters included with this system, allow the surgeon to offset the centerline between the

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stem and the femoral or tibial components throughout 360 degrees in the transverse axis. Titanium alloy Ti-6Al-4V bone screws can be used if additional screw fixation is warranted.

Intended Use: Cemented knee replacement device

Indications for Use:
The indications for the Vanguard™ 360 Revision Knee System are as follows:

1. Painful and disabled knee joint resulting from osteoarthritis, rheumatoid arthritis, 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 joint replacement procedure.

These devices are single-use implants intended for cemented use only.

Summary of Technologies: The technological characteristics (material, design and sizing) of the Vanguard™ 360 Revision Knee System are similar or identical to the predicate devices.

Non-Clinical Testing: Non-clinical laboratory testing was performed to determine substantial equivalence. Based on the information provided below, there are no new issues relating to safety or effectiveness introduced.

1. An Engineering Justification demonstrates that the cylindrical Boss geometry is capable of resisting *in-vivo* torque.
2. An Engineering Justification addressed the removal of the alignment tab from the femoral Boss
3. Verification testing of 80/20 Fatigue Strength demonstrated that all components passed testing.
4. Verification testing of Cantilever Beam Fatigue demonstrated that all components passed testing.
5. MRI Distortion testing was performed according to ASTM F2119-07. RF Heating tests were conducted in accordance with ASTM F2182-09. Testing of magnetically induced displacement force or torque deflection angle was measured to be 5° or less in the 3.0T MRI System in tests performed in accordance with ASTM F2052-06e1. MRI testing of the Vanguard Knee System components determined that the Vanguard System components are MR Conditional within the definition found in ASTM F2503-08.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Biomet Inc.
% Mr. Gary Baker
Regulatory Affairs Project Manager
56 East Bell Drive, P.O. Box 587
Warsaw, Indiana 46581

OCT 2 2 2010

Re: K093293
Trade/Device Name: Vanguard™ 360 Revision Knee System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH, MBV
Dated: October 18, 2010
Received: October 19. 2010

Dear Mr. Baker:

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,

Barbara Buch for

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

Enclosure

Indications for Use

510(k) Number (if known): K093293

OCT 2 2 2010

Device Name: Vanguard™ 360 Revision Knee System

The indications for the Vanguard™ 360 Revision Knee System are as follows:

1. Painful and disabled knee joint resulting from osteoarthritis, rheumatoid arthritis 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.

These devices are single-use implants intended for cemented use only.

Prescription Use YES (Part 21 CFR 801 Subpart D) AND/OR Over-the-Counter Use NO (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)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

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