K102580
p 1/2

MAR - 3 2011

510(k) Summary

Preparation Date:	January 3, 2010
Applicant/Sponsor:	Biomet Manufacturing Corp.
Contact Person:	Tamara West
Proprietary Name:	Vanguard® Removable Molded Poly Tibia
Common Name:	Knee Prosthesis
Classification Name:	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis (21CFR §888.3560)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

K060525	Vanguard Removable Molded Poly Tibia	Biomet Manufacturing Corp.
K915132	MCK [Maxim] Knee System	Biomet Manufacturing Corp.

Device Description:
The Vanguard® Removable Molded Poly Tibia (also referred to as the Vanguard® Mono-Lock) is intended to replace the tibial articulating surface in a joint replacement and works in conjunction with previously cleared Vanguard® Knee Systems. There are three parts to the Vanguard® Removable Cruciate Molded Polyethylene Tibia component: the tibial plate (Co-Cr-Mo), tibial bearing (UHMWPE) and an insert (Ti-6AL-4V).

The profile of the tibial plate is identical to that of the predicates. The stem geometry of the Vanguard® Removable Molded Poly Tibia is non modular and does not include the conical core geometry to house the female taper as the predicate K915132.

The articulation surface is identical to the surface cleared in K060525.

Intended Use: The Vanguard® Removable Molded Poly Tibia is intended for:
1. Painful and disabled knee joint resulting from osteoarthritis, rheumatoid arthritis traumatic arthritis where one or more compartments are involved;
2. Failure of a previous joint replacement procedure
3. Correction of varus, valgus, or post traumatic deformity;
4. Correction or revision of unsuccessful osteotomy or arthrodesis.

The device is a single use implant intended for use with bone cement.

K102580
p. 2/2

Summary of Technologies:
The technological characteristics (material, design, and sizing) of the Vanguard® Removable Molded Poly Tibia are identical to the predicate devices. The only change made to the Vanguard® Removable Molded Poly Tibia from the predicate device K060525 is to the stem design; the new device has a fixed cruciate stem whereas the predicate has a fixed I-beam stem. Additional sizes to the tibial plate and bearing include 59mm, 87mm and 91mm, which are identical to the predicate devices in K915132. The material, locking mechanism, and bearing articulation remain identical to the predicate devices. Therefore, Biomet believes the Vanguard® Removable Molded Poly Tibia is substantially equivalent to the previously cleared devices.

Non-Clinical Testing:
Mechanical testing was previously performed to determine substantial equivalence and the following test reports were provided in the predicate 510(k): CoCr I-Beam Tray 80/20 Fatigue Test Report, Removable Molded Tibia PS Post Fatigue Strength, 10mm PS Component – Intercondylar Polyethylene Thickness Analysis, Vanguard Removable Retention Test. The CoCr Cruciate Plate 80/20 Fatigue Test Report is also provided to further indicate the devices are functional within its intended use.

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

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 Manufacturing Corp.
% Ms. Tamara J. West
Senior Regulatory Affairs Specialist
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 465801

MAR - 3 2011

Re: K102580
Trade/Device Name: Vanguard® Removable Molded Poly Tibia
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: JWH
Dated: January 3, 2011
Received: January 7, 2011

Dear Ms. West:

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,

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): K102580

Device Name: The Vanguard® Removable Molded Poly Tibia

Indications For Use:

The Vanguard® Cruciate Molded Poly Tibia is intended for:

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

The device is a single use implant intended for use with bone cement.

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)

for M. Melkerson

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

510(k) Number K102580