K110362

FEB 28 2011

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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	Tamara West
Date prepared	February 4, 2011
Name of device	
Trade or proprietary name	Vanguard® Asymmetrical Patellar Component
Common or usual name	Knee Prosthesis
Classification name	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis (21CFR §888.3560)
Classification panel	Orthopedic
Regulation	21CFR §888.3560
Product Code(s)	JWH
Legally marketed device(s) to which equivalence is claimed	K040770 Vanguard Patellar Components K051977 Scorpio X3 UHMWPE Patellar Components
Reason for 510(k) submission	Addition of asymmetrical designed patella to the Vanguard® product line
Device description	The Vanguard® Patellar Component is machined of polyethylene (UHMWPE) conforming to ASTM F-648.
Intended use of the device	The Vanguard® Asymmetrical Patellar is intended for replacement of part of the knee joint in conjunction with a femoral and tibial component.
Indications for use	1. Painful and disabled knee joint resulting from osteoarthritis, rheumatoid arthritis traumatic arthritis where one or more compartments are involved;

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	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 un-cemented biological fixation application. Non-coated (Interlok®) devices and all polyethylene patellar components are indicated for cemented application only.

Summary of the technological characteristics of the device compared to the predicate

Characteristic	New Device	Predicate
Design	Asymmetrical or medialized dome	K051977 & K040770
Material	UHMWPE	K040770
Principal of operation	Primary replacement of a total knee joint	K040770
Dimensions	25, 28 & 31 x 8 mm 34 x 8.5 mm 37 & 40 x 10 mm	K040770

PERFORMANCE DATA

SUMMARY OF NON-CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE

Performance Test Summary-New Device

The Vanguard® Asymmetrical Patellar component has the same technological characteristics as the predicate devices except for a slight modification to the general design as described in this 510(k) notification. A risk analysis was conducted along with an engineering rationale to demonstrate equivalence of the subject products to the predicate devices.

Comparative Performance Information Summary

Characteristic	Requirement	New Device	Predicate Device
Patellofemoral Stability	Meet or exceed parameters	Meet	K921182
Contact Area Analysis	Meet or exceed parameters	Meet	K921182
Peg Shear Area Analysis	Meet or exceed parameters	Meet	K040770

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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.

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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.
% Ms. Tamara West
Senior Regulatory Affairs Specialist
56 East Bell Drive, POB 587
Warsaw, Indiana 46581-0587

FEB 2 8 2011

Re: K110362
Trade/Device Name: Vanguard® Asymmetrical Patellar components
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
Dated: February 04, 2011
Received: February 08, 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): K110362

Device Name: Vanguard® Asymmetrical Patella

Indications For Use:

The Vanguard® Asymmetrical Patella is intended for replacement of part of the knee joint in conjunction with a femoral and tibial component.

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.

Femoral components and tibial tray components with porous coatings are indicated for cemented and un-cemented biological fixation application. Non-coated (interlok) devices and all polyethylene patellar components are indicated for cemented application only.

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 K110362