FEB 29 2012

BIOMET
MANUFACTURING CORP.

510(k) Summary

Preparation Date: 28 November, 2011

Applicant/Sponsor: Biomet Manufacturing Corp.
56 East Bell Drive
P.O. Box 587
Warsaw, IN 46581-0857
Establishment Registration No. 1825034

Contact Person: Gary Baker, MS RAC
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Biomet Manufacturing Corp.
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Proprietary Name: Vanguard® Complete Knee System

Common Name: Knee Prosthesis

Classification Name: Knee joint patellofemorotibial metal/polymer porous- coated uncemented prosthesis (21CFR §888.3565)

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

Knee joint patellofemorotibial polymer+Additive/metal/polymer+Additive semi-constrained cemented prosthesis (21CFR §888.3560)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

K023546 Vanguard® CR Knee System
K033489 Vanguard® CR Knee System
K041046 Vanguard® PS+ Bearings
K050222 Vanguard® AS Tibial Bearings
K060303 Vanguard® PS Open Box Porous Femoral
K061340 Vanguard® Single Peg Patella
K080528 E1® Tibial Components (previously E-poly)

Device Description: The Vanguard® Complete Knee System is a total knee replacement system for either primary or revision knee arthroplasty. It consists of femoral components composed of cast Co-Cr-Mo per ASTM F-75 with either a porous plasma spray (PPS) or Interlok® surface finish, tibial bearings molded of polyethylene (UHMWPE) conforming to ASTM F-648 or machined of polyethylene (UHMWPE or UHMWPE with α-tocopherol) conforming to ASTM F-648, tibial trays (not part of this submission) and patellar components machined of polyethylene (UHMWPE) conforming to ASTM F-648.

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

Summary of Technologies: The Vanguard® Complete Knee System components have the same technological characteristics as the predicate components with the exception of the modifications described within this 510(k). Non-clinical testing was conducted to demonstrate that the modifications did not adversely affect safety and efficacy, and to demonstrate substantial equivalence to the predicate components.

Non-Clinical Testing: Mechanical testing was previously performed to determine substantial equivalence. All testing met or exceeded the established acceptance criteria. The following test reports were provided in the predicate 510(k)s.

Tibial-femoral Contact Area,
Patello-femoral Contact Area,
Patellofemoral Mechanical Stability,
Tibialfemoral Constraint,
Tibialfemoral Mechanical Stability,
Posterior Stabilized Fatigue,
Posterior Stabilized Static Load,
Range of Motion Analysis,
80/20 Femoral Fatigue,
Vanguard® PS Open Box Tensile Stress,
Constraint testing of AS and CR-L,
Contact Area Analysis (AS bearing),
Static Rotational Strength Test (PS+),
Varus/Valgus Constraint (PS+),
Tensile Strength E-poly,
Wear Testing E-poly, and
Contact Areas Analysis (patellar)

Clinical Testing: Clinical data is not necessary for a determination of substantial equivalence.

Conclusion: The Vanguard® Complete Knee System is substantially equivalent to previously cleared Biomet knee systems and do not raise any new issues of safety or efficacy.

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.
% Mr. Gary Baker, MS RAC
Senior Regulatory Affairs Specialist
56 East Bell Drive
Warsaw, Indiana 46580

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Re: K113550
Trade/Device Name: Vanguard Complete 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, MBH, OIY
Dated: November 28, 2011
Received: December 1, 2011

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.

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,

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): K113550

Device Name: Vanguard® Complete Knee System

Indications For Use:

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.

Prescription Use ___X___ (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

510(k) Number K113550