K102125
p 1/2

BIOMET
MANUFACTURING CORP.

FEB 2 3 2011

510(k) Summary

Preparation Date: 27 July, 2010

Applicant/Sponsor: Biomet Manufacturing Corp.

Contact Person: Gary Baker

Proprietary Name: Patient-Specific Vanguard™ Femoral Components

Common Name: Femoral components

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

Product Code: JWH

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

Maxim® Accel Knee System Interlok® Femoral Components – K023546 Biomet

Device Description:

The Patient-Specific Vanguard™ Femoral Components are comprised of a series of CoCrMo femoral components with each size offering an envelope of acceptable dimensions to allow for a fit that is specific to each patient, while still maintaining the Vanguard™ design. These components are intended for primary knee arthroplasty.

Intended Use: Cemented

Indications for Use:

The indications for the Patient-Specific Vanguard™ Femoral Components 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 applications.

Mailing Address:
P.O. Box 587
Warsaw, IN 46581-0587
Toll Free: 800.348.9500
Office: 574.267.6639
Main Fax: 574.267.8137
www.biomet.com

Shipping Address:
56 East Bell Drive
Warsaw, IN 46582

K102125
p2/2

Summary of Technologies: The technological characteristics (material, design and sizing) of the Patient-Specific Vanguard™ Femoral Components are similar or identical to the predicate devices.

Non-Clinical Testing: Non-clinical verification was performed to determine substantial equivalence. The results indicated that the device is functional within its intended use.

Clinical Testing: None provided as a basis for 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, Inc.
% Mr. Gary Baker, MS, RAC
65 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581-0587

FEB 2 3 2011

Re: K102125
Trade/Device Name: Patient-Specific Vanguard™ Femoral 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 9, 2011
Received: February 10, 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. 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): K102125

Device Name: Patient-Specific Vanguard™ Femoral Components

The indications for the Patient-Specific Vanguard™ Femurs 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)

for M. Melkerson

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

510(k) Number K102125