K061433 (pg 1 of 2)

BIOMET ORTHOPEDICS INC

AUG 2 1 2006

# 510(k) Summary

**Preparation Date:** May 23, 2006

**Applicant/Sponsor:** Biomet Manufacturing Corp.

**Contact Person:** Tracy Bickel Johnson, RAC

**Proprietary Name:** Vanguard™ Anatomic Patella Groove (APG) / Vanguard™ V Groove

**Common Name:** femoral and patella components

**Classification Name(s):**
- Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis (888.3560)
- Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis (888.3565)

**Legally Marketed Devices To Which Substantial Equivalence Is Claimed:** Vanguard™ (Maxim® Accel) -K023546 and K033489 (Biomet, Inc.), Vanguard™ Patella- K040770 (Biomet, Inc.), UHMWPE Components- K921182 (Biomet, Inc.), Avon™ PFJ Prosthesis – K041160, K020841, and K051948 (Stryker/Howmedica/Osteonics), Insall/Burstein® II – K872379 (Biomet, Inc.), Performance® Knee System -K874547 (Biomet, Inc.), NexGen® All-Poly Patella – K972270 (Zimmer Holdings), Duracon® CR – K032163 (Stryker/Howmedica/Osteonics)

**Device Description:**
The Vanguard™ Anatomic Patella Groove (APG) / Vanguard™ V Groove product line is a two piece system intended for use with additional tibial products to replace the patellofemorotibial joint space. The system is composed of one type of femoral and two types of patellae. The system can be used with any commercially available Biomet® Tibial Tray, Vanguard™ CR, CR-L, or AS bearing, or augment.

The femoral component is cruciate retaining (CR) in both left and right configurations. The femoral implants are available in both Interlok® and porous finish. The sizes of femoral implants range from: 55 - 80mm.

Two different all-polyethylene patellae designs will function with the new femoral components – a round, modified dome and a medially offset patella. Both designs have 3-pegs, concentric grooves, and cement pockets for cement fixation.

MAILING ADDRESS
P.O. Box 587
Warsaw, IN 46581-0587

SHIPPING ADDRESS
56 E. Bell Drive
Warsaw, IN 46582

OFFICE
574.267.6639 ■ FAX 574.267.8137 ■ E-MAIL biomet@biomet.com

K061433 (pg 2 of 2)

**510(k) Summary**
**Vanguard™ (APG) / Vanguard™ V Groove**
**Page 2 of 2**

**Intended 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 joint replacement procedure.

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 technological characteristics (material, design, sizing, indications) of the Vanguard™ APG are similar to or identical to the predicate devices.

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

**Clinical Testing:** None provided as a basis for substantial equivalence.

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All trademarks belong to Biomet, Inc. except the following:

Avon is a trademark of Stryker/Howmedica/Osteonics
Insall Burstein II is a trademark of Zimmer Holdings
NexGen is a trademark of Zimmer Holdings
Duracon CR is a trademark of Stryker/Howmedica/Osteonics

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 1 2006

Biomet Manufacturing Corp.
% Tracy Bickel Johnson, RAC
Manager, Regulatory Affairs
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K061433
Trade/Device Name: Vanguard™ Anatomic Patella Groove (APG) / Vanguard™ V Groove
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Codes: MBH, JWH
Dated: May 23, 2006
Received: May 24, 2006

Dear Ms. Johnson:

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.

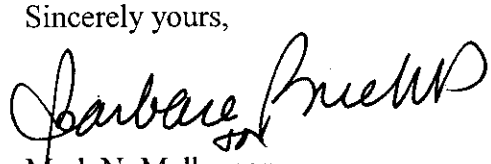
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



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

Enclosure

# Indications for Use

510(k) Number (if known): K061433

Device Name: Vanguard™ Anatomic Patella Groove (APG) / Vanguard™ V Groove

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 joint replacement procedure.

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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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buchman for MKM

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices



510(k) Number K061433