K060525

BIOMET

510(k) Summary

Preparation Date: 24 February 2006

MAY 25 2006

Applicant/Sponsor: Biomet Manufacturing Corp.

Contact Person: Tracy Bickel Johnson, RAC

Proprietary Name: Vanguard™ Removable Molded Polyethylene Tibia (Pop-Top)

Common Name: knee prostheses

Classification Name: JWH- prosthesis, knee, patellofemorotibial, semi-constrained, cemented, polymer/metal/polymer (888.3560)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed: Maxim® Removable Molded Polyethylene Tibia (Pop-Top) – K991753 and K984623 (Biomet, Inc.): Vanguard™ System- K023546 (Biomet, Inc.)

Device Description: Vanguard™ Removable Molded Polyethylene Tibia is intended to replace the tibial articulating surface in a joint replacement along with femoral components that were cleared in K023546. There are three parts to the Vanguard™ Removable Molded Polyethylene Tibia component: the tibial tray, tibial bearing, and an insert.

The I-beam profile of the tibial tray is identical to that of the Maxim® tibial tray cleared in the following submissions K984623 and K991753. The articulating surface is identical to the surface cleared in K023546.

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.

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

Summary of Technologies: The technological characteristics (direct molding UHMWPE onto the tibial tray and the Vanguard™ articulating surface) of the Vanguard™ Removable Molded Polyethylene Tibia 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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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 25 2006

Biomet Manufacturing Corp
c/o Mr. Tracy Bickel Johnson
56 East Bell Drive
PO Box 587
Warsaw, Indiana 46581

Re: K060525
Trade/Device Name: Vanguard Removable Molded Polyethylene Tibia
Regulation Number: CFR 888.3560
Regulation Name: Prosthesis, knee, patellofemorotibial, semi-constrained, cemented, polymer/metal/polymer
Regulatory Class: Class II
Product Code: JWH
Dated: February 24, 2006
Received: February 27, 2006

Dear Mr. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Herbert Lerner MD

for 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):

Device Name: Vanguard™ Removable Molded Poly Tibia

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.

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)

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

510(k) Number K060525