K050222

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AUG 16 2005

BIOMET

510(k) Summary

Applicant/Sponsor: Biomet Manufacturing Corp.
56 East Bell Drive
Warsaw, IN 46582
FDA Registration # 1825034

Contact Person: Gary Baker
Biomet Manufacturing Corp.
P.O. Box 587
Warsaw, IN 46581-0587
Telephone: (574) 267-6639 Ext. 1568
Fax: (574) 372-1683

Proprietary Name: Vanguard™ Anterior Stabilized Tibial Bearings.

Common Name: Knee Prosthesis

Classification Name: 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:
Maxim Accel (Vanguard™) CR – Lipped Tibial Bearings – K023546

Device Description: The Vanguard™ Anterior Stabilized Tibial Bearings are intended for use in the replacement of the articular portions of the knee joint. They offer increased anterior and posterior stabilization along with greater sagittal conformity. They are to be used with the Vanguard™ CR femoral components cleared in K023546 and the tibial tray components cleared in K915132, both of which were cleared for uncemented use in K033489. The system can utilize any Biomet commercially available patella button.

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.

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

Femoral components and tibial tray components with porous coating 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™ Anterior Stabilized Tibial Bearings have the same intended use, are made of the same materials and have the same or similar design and sizing as the predicate tibial bearings.

Non-Clinical Testing: Risk analysis has demonstrated equivalence between the modified and predicate devices.

Clinical Testing: No clinical testing was necessary to support the claim of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 16 2005

Mr. Gary Baker
Regulatory Specialist
Biomet Manufacturing Corp.
P.O. Box 587
Warsaw, Indiana 46581-0578

Re: K050222
Trade/Device Name: Vanguard™ Anterior Stabilized Tibial Bearings
Regulation Number: 21 CFR 888.3560, 21 CFR 888.3565
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis, Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis
Regulatory Class: II
Product Code: JWH, MBH
Dated: July 22, 2005
Received: July 26, 2005

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.

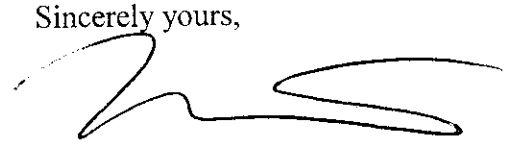
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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



for Mark N. Melkerson
Acting 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) K050222

Device Name: Vanguard™ Anterior Stabilized Tibial Bearings

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.

Femoral components and tibial tray components with porous coating are indicated for cemented and uncemented 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 _____
(Per 21 CFR 801 Subpart D) (Per 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 K050222