K042093

NOV - 1 2004

510(k) Summary

Sponsor: Biomet Manufacturing, Corp.
P.O. Box 587
Warsaw, IN 46581-0587

Contact Person: Tracy Bickel Johnson, RAC
Regulatory Associate
Biomet Manufacturing Corp.
(574) 267-6639

Proprietary Name: Vanguard M™ Series Unicondylar Tibial Bearings

Common Name: Molded Unicondylar Tibial Bearing

Classification Name: Prosthesis, knee, femorotibial, semi-constrained, cemented, metal/polymer (21 CFR 888.3530)

Substantially Equivalent Devices: Fixed Bearing Uni Component (K021621); Repicci II™ Unicondylar Knee (K971938); The Link® Endo-Model™ Sled Uni–Knee (K954186).

Device Description: The tibial component consists of ArCom®, ultrahigh molecular weight polyethylene (UHMWPE) plateau molded over a one-piece Co-Cr-Mo base and central keel. They are anatomic in geometry with right and left medial/lateral allocations.

Indications for Use: Partial replacement of the articulating surfaces of the knee when only one side of the joint is affected due to the compartmental primary degenerative or post-traumatic degenerative disease, previous tibial condyle or plateau fractures, deformity or revision of previous arthroplasty.

This device is intended to be used with bone cement.

Summary of Technologies: The Vanguard M™ Series Unicondylar Tibial Bearings are to be used with previously cleared Biomet Femoral components (K011138 and K971938). Additional thicknesses were added to the current system along with an update to the indications for use statement. The Vanguard M™ Series Unicondylar Tibial Bearings are similar and/or identical to the predicate devices in terms of material, function, indications, and labeling.

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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Tracy Bickel Johnson, RAC
Regulatory Associate
56 East Bell Drive
Biomet, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K042093
Trade/Device Name: Vanguard M™ Series Unicondylar Tibial Bearings
Regulation Number: 21 CFR 888.3530
Regulation Name: Knee joint femorotibial metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: HRY
Dated: August 2, 2004
Received: August 3, 2004

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

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/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, PhD, MD
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 M™ Series Unicondylar Tibial Bearings

Indications For Use:

Partial replacement of the articulating surfaces of the knee when only one side of the joint is affected due to the compartmental primary degenerative or post-traumatic degenerative disease, previous tibial condyle or plateau fractures, deformity or revision of previous arthroplasty.

This device is intended to be used with bone cement.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(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

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