FEB 1 1 2005

K042757

BIOMET

510(k) Summary

Applicant/Sponsor: Biomet Manufacturing Corp.
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581-0587

Contact Person: Gary Baker
Biomet Manufacturing Corp.
P.O. Box 587
Warsaw, Indiana 46581-0587
Phone: (574) 267-6639
FAX: (574) 372-1683

Proprietary Name: Vanguard™ SSK Knee System

Common Name: Knee prosthesis

Classification Name: Cemented semi-constrained polymer / metal / polymer knee prosthesis (21 CFR § 888.3560)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

Maxim Accel (Vanguard) Knee System – K023546 (Biomet Inc.)
Maximum Congruent Knee System – K9151332 (Biomet Inc.)

Device Description: The Vanguard™ SSK Knee System is a series of femoral components and tibial bearings designed to replace the articulating surfaces during knee replacement surgery.

Intended Use:

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.

Vanguard™ SSK components are intended for cemented use only.

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

Summary of Technologies: The Vanguard™ SSK Knee System components have the same intended use (knee joint replacement), the same functional characteristics (knee joint articulation), and are manufactured from the same materials as the predicate devices.

Non-Clinical Testing: The performance data indicated that the Vanguard™ SSK Knee System is substantially equivalent to the predicate devices for the uses indicated.

Clinical Testing: Clinical testing was not required for these components to support substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 11 2005

Mr. Gary Baker
Regulatory Specialist
Biomet Manufacturing Corp.
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K042757
Trade/Device Name: Vanguard SSK Knee System
Regulation Numbers: 21 CFR 888.3560
Regulation Names: Knee joint, patellofemorotibial, polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Codes: JWH
Dated: January 28, 2005
Received: January 31, 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.

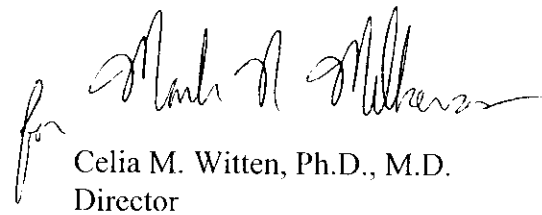
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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



Celia M. Witten, Ph.D., M.D.
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): K042757

Device Name: Vanguard™ SSK Knee System

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.

Vanguard™ SSK components are intended for cemented use only.

Prescription Use ___X___ AND/OR Over-the-Counter Use_____
(Per 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)

for Mark N. Milhous

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

K042757

510(k) Number