DEC 1 8 2003

K031804

BIOMET

510 (K) Summary

Applicant or Sponsor: Biomet, Inc.
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581-0578

Contact Person: Gary Baker
Phone: (574) 267-6639 Extension 1568

Proprietary Name: ComPreSs™ Distal Femoral Replacement.

Common Name: Segmental Femoral Stem Component.

Classification: Prosthesis, Knee, Femorotibial, Constrained, Cemented, Metal/Polymer (21 CFR §888.3510)

Product Code: KRO

Device Classification: Class II

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

1. Finn Knee System - Biomet Inc. (K945028)
2. Modular Replacement System – Howmedica Inc. (K972401)

Device Description:

The ComPreSs™ Distal Femoral Replacement is a metallic femoral segmental fixation stem intended to replace the distal part of the femur in cases of severe bone loss. The design of the ComPreSs™ stem allows a compressive load to be applied at the prosthetic implant-bone interface at the time of device insertion. This is accomplished through a spring system built into the stem.

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Indications for Use:

The ComPreSs™ Distal Femoral Replacement System is indicated for tumors of the distal femur and revisions of oncologic distal femoral replacements.

The ComPreSs™ Distal Femoral Replacement components are intended for uncemented use.

Summary of Technologies:

The ComPreSs™ Distal Femoral Replacement is made of the same material as the predicate device. Unlike the predicate device, the ComPreSs™ Distal Femoral Replacement components are intended for uncemented use.

Non-Clinical Testing:

Results of mechanical testing showed that the ComPreSs™ Distal Femoral Replacement produces less stress shielding than a standard cemented implant. Testing also addressed all failure mechanisms for the device, and was found to be strong enough to begin the clinical study.

Clinical Results:

The clinical results determined that the ComPreSs™ Distal Femoral Replacement is substantially equivalent to similar knee prostheses implanted for similar indications.

Summary:

Based on the results of mechanical testing and clinical data, the ComPreSs™ Distal Femoral Replacement is substantially equivalent to the predicate device.

All trademarks are property of Biomet, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 8 2003

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

Re: K031804
Trade Name: ComPreSs™ Distal Femoral Replacement
Regulation Number: 21 CFR 888.3510
Regulation Name: Knee joint femorotibial metal/polymer constrained cemented prosthesis
Regulatory Class: II
Product Code: KRO
Dated: September 24, 2003
Received: September 25, 2003

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.

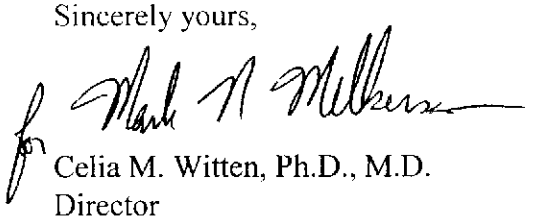
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4659. 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,



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

510(k) Number (IF KNOWN): K031804

Device Name: ComPreSs™ Distal Femoral Replacement

Indications for Use:

The ComPreSs™ Distal Femoral Replacement System is indicated for tumors of the distal femur and revisions of oncologic distal femoral replacements.

The ComPreSs™ Distal Femoral Replacement components are intended for uncemented use.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X (Per 21 CFR 801.109) OR Over-the-Counter Use ____ (Optional Format 1-2-96)

for Mark N Melkerson

(Division Sign-Off)
Division of General Restorative Devices

510(k) Number K031804