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JUL 3 0 2004

BIOMET

510(k) Summary

Applicant or 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: ComPreSs® Distal Femoral Replacement

Common Name: Segmental Femoral Stem Component

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

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

1. ComPreSs® Distal Femoral Replacement – Biomet Inc. (K031804).
2. Modular Replacement System – Howmedica Inc. (K972401).
3. Finn® Knee System – Biomet Inc. (K945028).
4. Oncology Salvage System - Biomet Inc. (K002757).

Device Description:

The ComPreSs® Distal Femoral Replacement System consists of three main components, the anchor plug, the spindle assembly, and the intercalary segment. The Anchor Plug is embedded within the medullary canal, the Spindle Assembly attaches to the Anchor Plug and is compressed against the bone / implant interface at the osteotomy site. The Intercalary Segment attaches to the Spindle Assembly, and completes the Femoral Stem Component.

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P.O. Box 587
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56 E. Bell Drive
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574.267.6639

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574.267.8137

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biomet@biomet.com

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Intended Use: The ComPreSs® Distal Femoral Replacement System is intended for uncemented use.

Indications for Use: The ComPreSs® Distal Femoral Replacement System is intended for:

1. Correction of revision of unsuccessful osteotomy, arthrodesis, or previous joint replacement
2. Tumor resections
3. Revision of previously failed total joint arthroplasty
4. Trauma

Summary of Technologies: The Hydroxyapatite coated spindles are identical in material, function, design, and sizing as the predicate spindles. The only change is the addition of Hydroxyapatite coating. The ComPreSs® / OSS / Finn® Taper Adapters are made of the same material, with the same taper geometries as the predicate OSS tapers, the ComPreSs® Distal Femoral Replacement tapers, or the Finn® tapers included in the predicate ComPreSs® Distal Femoral Replacement.

Non-Clinical Testing: Mechanical testing was done on the tapers. This testing, along with engineering justification, indicated that the tapers incorporated into these components are substantially equivalent to the tapers used in the predicate devices. The Hydroxyapatite coating on the Hydroxyapatite coated spindles was previously tested with porous coating, and the testing concluded that the addition of Hydroxyapatite coating did not weaken the devices tested.

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

JUL 3 0 2004

Mr. Gary Baker
Regulatory Specialist
Biomet Manufacturing Corporation
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581

Re: K041352
Trade/Device Name: ComPreSs® Distal Femoral Replacement System
Regulation Number: 21 CFR 888.3510
Regulation Name: Knee joint femorotibial metal/polymer constrained cemented prosthesis
Regulatory Class: II
Product Code: KRO
Dated: May 19, 2004
Received: May 20, 2004

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.

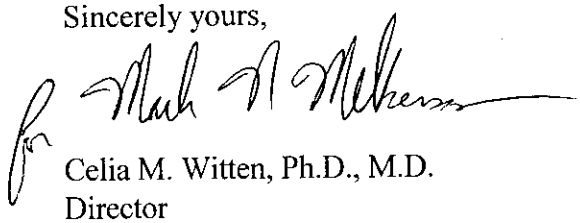
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

Indications For Use

510(k) Number (IF KNOWN): K041352

Device Name: ComPreSs® Distal Femoral Replacement System.

Indications for Use:

1) Correction of revision of unsuccessful osteotomy, arthrodesis, or previous joint replacement

2) Tumor resections

3) Revision of previously failed total joint arthroplasty

4) Trauma

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

Prescription Use ✓ 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)

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

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