MAY 0 6 2002

K020381
page 1 of 2

BIOMET
CORPORATE HEADQUARTERS

Summary of Safety and Effectiveness

Applicant/Sponsor: Biomet Orthopedics, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

Contact Person: Patricia Sandborn Beres
Senior Regulatory Specialist
Telephone: (574) 267-6639
Fax: (574) 372-1683

Proprietary Name: Expandable Knee

Common Name: Knee replacement prosthesis

Classification Name: Prosthesis, knee, femorotibial, constrained, cemented, metal/polymer (888.3510)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed: Substantial equivalence is claimed to Biomet's Finn® Knee System (K945028) and Oncology Salvage System (K002757).

Device Description: The Expandable Knee is an additional component to Biomet's Oncology Salvage System that gives the surgeon the ability to expand the prosthesis as a patient grows. All expansion takes place where the natural bone has been removed. The device does not "lengthen" existing bones.

The devices are available in two styles or expansion mechanisms: a clip-style and a screw-style. The clip-style is available as either a one-piece unit with an integrated distal femoral surface or as a diaphyseal segment for use with the distal femoral replacement component of Biomet's Oncology Salvage System constrained knee system. Clip-style devices are available in 7 initial replacement lengths of 13cm to 19cm providing an additional expansion from 3cm to 9cm. The screw-style expandable segment relies on movement of a screw for expansion. The device has an integrated distal femoral component. The screw-style Expandable Knee is available in 11 sizes providing a maxim

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expansion from 3cm to 13cm. A series of intramedually stems form 9mm to 19mm in diameter are available for cemented fixation of the stem into the remaining femoral bone. In addition to a set number of sizes, Biomet will offer customized components designed to more closely match patient anatomy. These components will be designed within a pre-defined envelope.

.All types of expandable components are intended for use with components of Biomet's Oncology Salvage System.

Intended Use: The Expandable Knee offers a treatment option for patients requiring distal femoral replacement who have not yet achieved full skeletal maturity (open epiphysis) or patients who require surgery who have significant residual leg length discrepancy. Indication for use of this device is most commonly tumor resection but could also involve osteoarthritis; rheumatoid arthritis; correction of deformity; and correction or revision of unsuccessful osteotomy, arthrodesis or previous joint replacement. The devices are single use implants intended for implantation with bone cement.

Summary of Technologies: The materials, surface finishes, and processing of the Expandable Knee are similar to the predicate devices.

Non-Clinical Testing: Mechanical analysis of both the screw-type and clip-type Expandable Knee has been conducted. Analysis showed that the strength of the expandable devices exceeds that of the clinically success predicate Finn® Knee device. Fatigue testing of the screw-type (worst-case) device has been conducted. This testing showed that the screw mechanism could successfully withstand anatomic loading conditions at maxim expansion. The testing also demonstrated that the expansion mechanism remained functional after fatigue.

Clinical Testing: None provided

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 0 6 2002

Ms. Patricia Sandborn Beres
Senior Regulatory Specialist
Biomet Orthopedics, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K020381
Trade/Device Name: Expandable Knee
Regulation Number: 21 CFR 888.3510
Regulation Name: Knee joint femorotibial metal/polymer constrained cemented prosthesis
Regulatory Class: II
Product Code: KRO
Dated: January 30, 2002
Received: February 5, 2002

Dear Ms. Beres:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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, 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): K020381

Device Name: Expandable Knee

Indications For Use:

The Expandable Knee offers a treatment option for patients requiring distal femoral replacement who have not yet achieved full skeletal maturity (open epiphysis) or patients who require surgery who have significant residual leg length discrepancy. Indication for use of this device is most commonly tumor resection but could also involve osteoarthritis; rheumatoid arthritis; correction of deformity; and correction or revision of unsuccessful osteotomy, arthrodesis or previous joint replacement.

The devices are single use implants intended for implantation with bone cement.

for Mark N Milhous

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

510(k) Number K020381

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ___ OR Over-The-Counter Use
(Per 21 CFR 801.109)

(Optional Format 1-2-96)