

K974558

MAR - 4 1998

Summary of Safety and Effectiveness

Sponsor: Biomet, Inc.
 Airport Industrial Park
 P.O. Box 587
 Warsaw, IN 46581-0578

Device: Total Femur Replacement

Classification Name: Prosthesis, Hip, semi-constrained, metal/polymer, cemented (888.3350)

Device Description: The Salvage/Oncology Hip and Total Femur System is designed to replace either the entire femur or a large portion of the proximal femur in cases of severe bone loss most commonly due to oncological diagnoses or limb salvage following multiple revisions or trauma.

When total femoral replacement is indicated, a proximal 1/3 hip component, a diaphyseal shaft and Finn Knee components are necessary. When the device is used for hip replacement, a proximal 1/3 hip component and a femoral stem are required. Two styles of the proximal 1/3 hip component are available, the Letson Modular Proximal and the Finn Proximal Component. Both devices have left and right configurations to ensure proper alignment of components. The proximal 1/3 hip component devices can be used as a modular hip stem with a femoral stem in cases where large proximal femur bone resection is necessary but the knee joint is not involved. The stems compatible with the proximal components are the Finn Knee Modular Segmental Stem Components. The diaphyseal component is a shaft which connects a proximal 1/3 hip component to a knee component when the device is used for total femur replacement.

All components of this system are indicated for use with bone cement.

Potential Risks: The potential risks associated with this device are the same as with any joint replacement device. These include, but are not limited to:

| | | |
|----------------------------------|----------------------------|----------------|
| Reaction to the bone cement | Blood vessel damage | Bone fracture |
| Deformity of the joint | Soft tissue imbalance | Infection |
| Cardiovascular disorders | Delayed wound healing | Hematoma |
| Fracture of the cement | Metal sensitivity | Dislocation |
| Implant loosening/migration | Fracture of the components | Excessive wear |
| Breakdown of the porous surface | Tissue growth failure | Nerve damage |
| Disassociation of the components | | |

Substantially Equivalent Devices: Biomet's Proximal Femoral Hip Replacement 510(k) K810258 cleared 3/5/81; Biomet's Mallory/Head Modular Calcar 510(k) K945115 cleared 5/2/95; Wright Medical Technology's S.O.S. Proximal Femur 510(k) K933281 cleared 6/7/94



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Patricia Sandborn Beres
Director, Regulatory Affairs
Biomet, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

MAR - 4 1998

Re: K974558
Trade Name: Salvage/Oncology Hip and Total Femur System
Regulatory Class: II
Product Codes: JDI and KRO
Dated: December 3, 1997
Received: December 5, 1997

Dear Ms. Beres:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

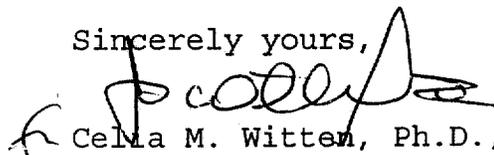
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Ms. Patricia Sandborn Beres

This letter will allow you to begin marketing your device as described in your 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 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,


Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K974558

Device Name: Salvage/Oncology Hip and Total Femur System

Indications For Use:

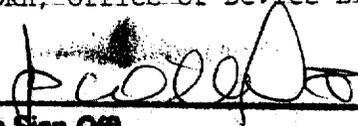
The Salvage/Oncology Hip and Total Femur System is designed to replace the either the entire femur or a large portion of the proximal femur in cases of severe bone loss most commonly due to oncological diagnoses or limb salvage following multiple revisions.

The device requires the use of a modular head, acetabular component and when used as a total femur replacement a Finn Knee tibial component.

All components of this system are indicated for use with bone cement.

(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)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K974558

Over-The-Counter Use _____

(Optional Format 1-2-96)