

JAN - 7 2000

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K994326

SUMMARY OF SAFETY AND EFFECTIVENESS

Sponsor: Biomet Inc.
Airport Industrial Park
P.O. Box 587
Warsaw, IN 46581-0587

Contact Person: Tracy J. Bickel
(219) 372-1761

Device(s): Ascent Knee System

Intended Use:

The indications for use of the Ascent Knee are the same as for other conventional knee prostheses. These include the relief of pain and restoration of motion due to non-inflammatory degenerative joint diseases, rheumatoid arthritis, deformities of the knee, and revisions of previously failed knee replacements.

This device is for use with bone cement

Classification: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis (CFR 888.3560)

Device Description: There are two components introduced into the Ascent Knee System which are as follows: the XXL cobalt chrome femoral component and the XXL titanium femoral augments.

Primary Femoral Component

The Ascent primary femoral component is available in either porous or Interlok finishes. The femoral component is composed of cast cobalt chromium (Co-Cr-Mo), conforming to ASTM specification F-75.

Augments

The Ascent Knee System has independent Ti-6Al-4V femoral augments, which are designed to replace damaged or diseased bone. There are two types of augments available, posterior and distal augments. The posterior augments come in 4mm and 8mm thicknesses, while the distal augments are available in 4, 8, and 12mm thicknesses. The posterior and distal augments are available in 6 sizes.

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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 bone cement
Deformity of the joint
Cardiovascular disease
Fracture of the cement
Implant loosening/migration
Tissue growth failure

Blood vessel damage
Soft tissue imbalance
Delayed wound healing
Metal sensitivity
Fracture of the components
Nerve damage

Bone fracture
Infection
Hematoma
Dislocation
Excessive wear



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Tracy J. Bickel
Regulatory Specialist
Biomet Manufacturing Inc.
Airport Industrial Park
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K994326
Trade Name: Ascent XXL Primary Femoral Component and XXL Femoral Augments
Regulatory Class: II
Product Code: JWH
Dated: December 17, 1999
Received: December 22, 1999

Dear Ms. Bickel:

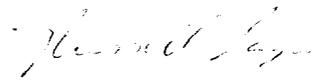
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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). 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 requirements, 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.

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) 594-4559. 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 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/dsma/dsmamain.html>".

Sincerely yours,



James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K994326
Device Name: Ascent Knee System
Indications for Use:

The Ascent Knee System is indicated for:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use
(Optional Format 1-2-96)



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K994326

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