K024037

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Summary of Safety and Effectiveness

DEC 3 0 2002

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

Contact Person: Patricia Sandborn Beres
Senior Regulatory Specialist
Telephone: (219) 267-6639
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Proprietary Name: Narrow Ascent™ Interlok® Femoral Components

Common Name: Knee replacement femoral component

Classification Name: Knee joint patello-femorotibial polymer/metal/polymer semi-constrained cemented prosthesis (21 CFR 888.3560)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed: Ascent™ Primary Interlok® Femur previously cleared in 510(k) K982869.

Device Description: The Narrow Ascent™ Interlok® Femoral Components are primary femoral components intended for use with an Ascent™ tibial component and patella for total knee replacement. The device is manufactured from cast cobalt alloy (Co-Cr-Mo) conforming to ASTM F-75 with Biomet's Interlok®, 30 grit blasted finish. Three sizes, x-small, small, and medium are available in left and right configurations.

The device varies from the predicated device in that the width of the component in the medial-lateral direction has been reduced by approximately 4mm. This has been accomplished by reducing the width of each condyle by approximately 2mm. All other dimensions remain the same. A narrower femoral component is desired to avoid overhang of the device in a patient with a naturally narrow femur.

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Intended Use:

1) Painful and disabled knee joint resulting from osteoarthritis, rheumatoid arthritis, traumatic arthritis where one or more compartments are involved.
2) Correction of varus, valgus, or posttraumatic deformity.
3) Correction or revision of unsuccessful osteotomy, arthrodesis, or failure or previous joint replacement procedure.

Summary of Technologies: The materials, design and processing of the modified device are identical to or similar to the predicate.

Non-Clinical Testing: Engineering analysis was provided to demonstrate that the design change would not compromise the strength of the component.

Clinical Testing: None provided.

Ascent and Interlok are trademarks of Biomet, Inc.
Tyvek is a trademark of E.I. duPont de Nemours and Company

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 3 0 2002

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

Re: K024037
Trade/Device Name: Narrow Ascent™ Interlok® Femoral Components
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH
Dated: December 5, 2002
Received: December 6, 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,

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): K024057

Device Name: Narrow Ascent™ Interlok® Femoral Components

Indications For Use:

1) Painful and disabled knee joint resulting from osteoarthritis, rheumatoid arthritis, traumatic arthritis where one or more compartments are involved.
2) Correction of varus, valgus, or posttraumatic deformity.
3) Correction or revision of unsuccessful osteotomy, arthrodesis, or failure or previous joint replacement procedure.

The device is indicated for implantation with cement.

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

510(k) Number K024057

(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)