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K021641
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BIOMET

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SUMMARY OF SAFETY AND EFFECTIVENESS

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

Contact Person: Dalene T. Binkley
Telephone: (219) 267-6639

Proprietary Name: Ringloc® Constrained Liner

Common Name: Constrained Acetabular Insert

Classification: Prosthesis, hip, constrained, metal/polymer (CFR 888.3310).

Device Classification: Class II

Legally Marketed Device to which Substantially Equivalence is Claimed: Johnson & Johnson S-ROM® Poly-Dial Constrained Liner PMA #P960054 and Osteonics Constrained Acetabular Insert PMA #P960047.

Device Description: The Ringloc® Constrained Acetabular Liners are polyethylene liners with a 10° beveled inner edge that, with a locking ring, captures the modular head.

Indications for Use: The Ringloc® Constrained Liners are indicated for use as a component of a total hip prosthesis in primary and revision patients at high risk of dislocation due to a history of prior dislocation, bone loss, joint or soft tissue laxity, neuromuscular disease, or intra-operative instability, and for whom all other options to constrained acetabular components have been considered.

Summary of Technologies: The Ringloc® Constrained Liner-the materials, design, sizing, and indications are similar or identical to the predicate devices.

Non-Clinical Testing: Mechanical testing, published medical literature, and engineering justifications determined that the Ringloc® Constrained Liner presented no new risks and is, therefore, substantially equivalent to the predicate device.

MAILING ADDRESS
P.O. Box 587
Warsaw, IN 46581-0587

SHIPPING ADDRESS
56 E. Bell Drive
Warsaw, IN 46582

OFFICE
574.267.6639 ■ FAX
574.267.8137 ■ E-MAIL
biomet@biomet.com

Clinical Testing: This device was part of the Ringloc® Constrained Liner Clinical Study- IDE #G990138. Please refer to the clinical data in the annual progress report that was submitted to the FDA on March 8, 2002.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 5 2002

Ms. Dalene T. Binkley
Regulatory Affairs Specialist
Biomet, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K021661
Trade Name: RingLoc® Constrained Liner
Regulation Number: 21 CFR 888.3310
Regulation Name: Hip joint metal/polymer constrained cemented or uncemented prosthesis
Regulatory Class: II
Product Code: KWZ
Dated: August 19, 2002
Received: August 20, 2002

Dear Ms. Binkley:

We have reviewed your Section 510(k) premarket 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) 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.

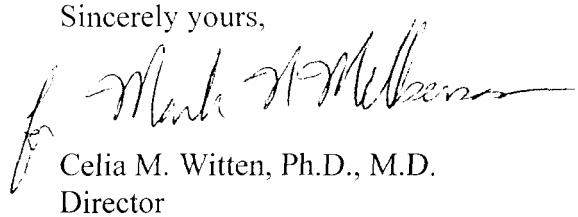
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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): K021661

DEVICE NAME: Ringloc® Constrained Liner

INDICATIONS FOR USE:

The Ringloc® Constrained Liner is indicated for use as a component of a total hip prosthesis in primary and revision patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, joint or soft tissue laxity, neuromuscular disease, or intra-operative instability, and for whom all other options to constrained acetabular components have been considered.

(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)

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

510(k) Number K021661