K030047

BIOMET

JAN 2 3 2003

SUMMARY OF SAFETY AND EFFECTIVENESS

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

Contact Person: Max T. Hebel
Telephone: (219) 267-6639

Proprietary Name: Freedom™ Constrained Liners

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: Ringloc® II Constrained Liners (K021728)

Device Description: The Freedom™ Constrained Acetabular Liners are polyethylene liners that will come pre-assembled with a retaining ring already in place. The liners will be available in five different styles. All the liners allow for the same range of motion. The locking mechanism and profile of that mechanism remain the same throughout the series.

Indications for Use: The Freedom™ 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 Freedom™ Constrained Liners-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 Freedom™ Constrained Liner presented no new unacceptable risks and is, therefore, substantially equivalent to the predicate device.

Clinical Testing: None provided as a basis for substantial equivalence.

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Warsaw, IN 46582

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 23 2003

Mr. Max T. Hebel
Regulatory Affairs Specialist
Biomet, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K030047
Trade Name: Freedom™ 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: January 2, 2003
Received: January 6, 2003

Dear Mr. Hebel:

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), please contact the Office of Compliance at (301) 594-4659. 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 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): _____
Device Name: **Freedom™ Constrained Liners**
Indications for Use:

The Freedom™ Constrained Liners are intended to replace a hip joint. The devices are intended for general use in skeletally mature individuals undergoing primary and/or secondary revision surgery at high risk of hip dislocation due to a history of prior dislocation, joint or bone loss, soft laxity, neuromuscular disease, or intra-operative instability and for whom all other options to constrained acetabular components have been considered.

for Mark N Melkerson
MNM
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K030047

(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)