

JUL 8 1999

## Summary of Safety and Effectiveness

**Proprietary Name:** Titanium Low Profile Screws

**Classification Name:** Prosthesis, hip, semi-constrained, metal/polymer, porous, uncemented (888.3358)

**Device Product Code:** 87LPH

**Intended Use:** To provide fixation of any acetabular cup, with appropriate sized screw holes, to the pelvic bone during total hip replacement procedures.

**Indications for Use:** Total hip replacement procedures for:

- 1) Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis
- 2) Rheumatoid arthritis
- 3) Correction of functional deformity
- 4) Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques
- 5) Revision procedures where other treatments have failed

The device is intended for insertion without bone cement. It is a single use implant.

**Device Description:** Biomet Titanium Low Profile Screws are available in 5.0mm and 6.5mm diameters in lengths from 15mm to 70mm. The 5.0mm screws are for use in screw holes on the rim of an acetabular shell whereas the 6.5mm screws are designed for use in the dome of an acetabular shell. Each screw has a self-tapping point.

**Substantial Equivalence:** Biomet's Low Profile Screws are substantially equivalent to acetabular screws depicted with the following competitive acetabular systems:

Trilogy Acetabular System – Zimmer	510(k) K934765
Arthopor Acetabular System – Joint Medical Products Corp.	510(k) K955511

**Potential Risks:** The potential risks associated with this device are the same as other metallic implants. These include, but are not limited to:

Blood vessel damage	Bone fracture	Deformity of the joint
Soft tissue imbalance	Infection	Cardiovascular disorders
Delayed wound healing	Hematoma	Metal sensitivity
Implant loosening	Implant fracture	Implant migration
Dissociation of components	Excessive wear	Nerve damage



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUL 8 1999

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

Re: K991807  
Trade Name: Titanium Low Profile Acetabular Screws  
Regulatory Class: II  
Product Code: LPH  
Dated: May 24, 1999  
Received: May 26, 1999

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.

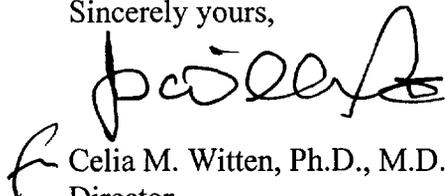
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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,

A handwritten signature in black ink, appearing to read "C. Witten", is written over the typed name.

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): K991807

Device Name: Titanium Low Profile Screws

Indications For Use: Total hip replacement procedures for:

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- 3) Correction of functional deformity
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- 5) Revision procedures where other treatments have failed

The devices are single use implants.

Intended Use: To provide fixation of any acetabular cup, with appropriate sized screw holes, to the pelvic bone during total hip replacement procedures.

(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)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

  
(Division Sign-Off)

Division of General Restorative Devices

510(k) Number

K991807