

JUN - 5 2000

K993874

## 510(k) Summary of Safety and Effectiveness

November 12, 1999

Hartmut Loch, C.E.O.  
PLUS Orthopedics  
San Diego, CA

- Trade name:** BOFOR Revision Cup
- Common name:** Cementless Acetabular Cup
- Classification name:** Prosthesis, hip, metal/ceramic/polymer, semi-constrained cemented or nonporous uncemented 21 CFR 888.3353 (87 LZO)
- Equivalence:** Howmedica Osteolock Acetabular Shell System (K971854, SE date 07-30-97) and Howmedica Osteolock Acetabular Cup (K981201, SE date 05-29-98).
- Characteristics:** The BOFOR Revision Cup consists of a titanium shell (Ti 6Al 4V) and an UHMWPE insert with a pure titanium cover shell. The BOFOR cup is asymmetrical and elongated, giving it a slightly "bean-shaped" design. This bean shape gives better three-point anchorage and provides better protection for the posterior column of the acetabulum. Other features of the BOFOR cup include a decentralized acetabulum inlay, cancellous bone screw anchorage, external fixation ribs, and a cranial keel, which acts as an adjuvant support column. The BOFOR cup comes in six sizes with compatible PE inserts in three sizes.
- Indications:** The BOFOR Revision Cup is intended to be used to replace the acetabulum in revision hip arthroplasty.
- Contraindications:** Contraindications include acute or chronic infections (local or systemic) or a history of infection; severe muscular, neurological, or vascular deficiencies which compromise the affected extremity; bone defects or insufficient bone quality which may affect the stability of the implant; any concomitant illness which may compromise the function of the implant; severe obesity; allergy to the implant materials; subluxation of the femur against the eminentia; ligament instability; severe varus or valgus misalignment; retropatellar degenerative arthritis; extension contractures over 10°.
- Performance data:** Biomechanical Testing has been provided. All test results are sufficient for *in vivo* loading.

**JUN - 5 2000**Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Hartmut Loch  
Chief Executive Officer  
PLUS Orthopedics  
3550 General Atomics Court  
Bldg. 15-100  
San Diego, California 92121-1122

Re: K993874  
Trade Name: BOFOR Revision Cup  
Regulatory Class: II  
Product Code: LZO  
Dated: March 30, 2000  
Received: March 31, 2000

Dear Mr. Loch:

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 control provisions of the Act. The general control 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.

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.

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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 at (301) 443-6597, or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in cursive script that reads "Celia M. Witten".

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): K993874

Device Name: BOFOR Revision Cup

Indications for Use:

The BOFOR Revision Cup is intended to be used to replace the acetabulum in revision hip arthroplasty.

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Dan R. Lochner  
(Division Sign)  
D  
S: K993874

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use

(Optional Format 1-2-96)