K992153

SEP 23 1999

510(k) Summary of Safety and Effectiveness

June 25, 1999

Trade name:	PE-PLUS Acetabular Cup
Common name:	Cemented Acetabular Cup
Classification name:	Prosthesis, hip, semi-constrained, metal/polymer, cemented 21 CFR 888.3350 (87 JDI)
Equivalence:	Implex HEP Acetabular Cup System, Cemented (K971705, 08-06-97); Howmedica Duration Stabilized UHMWPE Exeter All Plastic Acetabular Component (K972792, 10-16-97)
Characteristics:	The PE-PLUS Acetabular Cup is made of an ultra high molecular weight polyethylene (ASTM F 648) and accommodates three ball head sizes (diameters of 22, 28, and 32). Twelve sizes are available for the 22 and 28 head diameters, (cup sizes 42 to 64, in 2mm increments) and nine cup sizes for the 32 head diameter (cup sizes 48 to 64, in 2mm increments).
Indications:	The PE-PLUS Acetabular Cup is intended for cemented use in hip arthroplasty where the acetabular socket needs restructuring.
Contraindications:	Contraindications include acute or chronic infections (local or systemic), serious lesions of muscles, nerves or blood vessels, which put the affected limb at risk, bony defects or poor bone quality, which might endanger the stability of the prosthesis, and any concurrent disease, which might interfere with the function of the implant.
Performance data:	Extensive literature has been provided.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 23 1999

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

Re: K992153
PE-Plus Acetabular Cup
Product Code: JDI
Class: II
Dated: June 25, 1999
Received: June 25, 1999

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 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.

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

Sincerely yours,

for 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): K992153

Device Name: PE-PLUS Acetabular Cup

Indications For Use:

The PE-PLUS Acetabular Cup is intended for cemented use in hip arthroplasty where the acetabular socket needs restructuring.

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K992153

Prescription Use X
(Per 21 CFR 801.109)