

3/15/99

K990309

**510(k) Summary of Safety and Effectiveness**

February 19, 1999

- Trade name:** PLUS Fracture Head Prosthesis
- Common name:** Prosthesis, hip, femoral head
- Classification name:** Hip Joint Femoral (Hemi-Hip) Metallic Cemented or Uncemented Prosthesis 21 CFR 888.3360 (87 KWL)
- Equivalence:** Johnson & Johnson ULTIMA Unipolar Head (K965156, SE date 01/24/97) and the Foundation Unipolar Femoral Head (K973614, SE date 12/18/97).
- Characteristics:** The PLUS Fracture Head Prosthesis comes in 12 different sizes and in two neck lengths. The PLUS Fracture Head Prosthesis is made of CoCrMo and its highly polished metal surface minimizes friction between the implant and the acetabulum. The standard cone allows various possible combinations with all PLUS hip stems. This makes it possible to obtain better stress distribution, which can reduce wear on the acetabulum and pain for the patient. The PLUS Fracture Head Prosthesis can be changed into a total hip prosthesis without replacing the femoral components.
- Indications:** The PLUS Fracture Head Prosthesis is intended for use in fractures of the femoral neck and fractures or avascular necrosis of the femoral head with all PLUS hip stem prostheses, which have the appropriate 12/14 Morse Taper.
- 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.
- Performance data:** None provided at this time.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAR 15 1999

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

Re: K990309  
Trade Name: PLUS Fracture Head Prosthesis  
Regulatory Class: II  
Product Code: KWL  
Dated: January 29, 1999  
Received: February 1, 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.

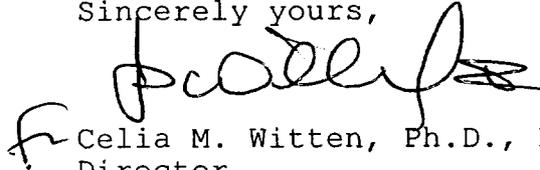
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

Page 2 - Mr. Hartmut Loch

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,



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):   K 990309  

Device Name: PLUS Fracture Head Prosthesis

Indications for Use:

The PLUS Fracture Head Prosthesis is intended for use in fractures of the femoral neck and fractures or avascular necrosis of the femoral head with all PLUS hip stem prostheses, which have the appropriate 12/14 Morse Taper.

**(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)**

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Device Sign Off)

Device Name: PLUS Fracture Head Prosthesis

510(k) Number

  K990309  

Prescription Use   X    
(Per 21 CFR 801.109)  
(Optional Format 1-2-96)

OR

Over-The-Counter-Use