

K982059

## 510(k) Summary of Safety and Effectiveness

August 14, 1998

- Trade name:** UC-PLUS Solution Unicondylar Knee System
- Common name:** Knee Joint Prosthesis
- Classification name:** Knee Joint Femorotibial Metal/Polymer Semi-Constrained Cemented Prosthesis (21 CFR 888.3530, 87HRY)
- Equivalence:** P.F.C. Sigma Uni-Compartmental Knee System (Johnson & Johnson), K954481, SE date 10/10/96
- Characteristics:** The UC-PLUS Solution Unicondylar Knee System consists of a femoral component and a tibial component. The femoral component is made of a cobalt chrome cast alloy and is 4mm thick. Symmetrical components can be used with right or left. The cement pockets are continuous for a minimal cement thickness of 1mm. The femoral component is available in 5 sizes. The tibial component has a flat articulating surface which provides more flexibility. The all-poly tibial component is made of UHMWPE. A cemented metal back tibial component is also available, made of cobalt chrome cast alloy and a UHMWPE insert. Both tibial components come in 5 sizes, 4 thicknesses each. All materials conform to ASTM standards.
- Indications:** The UC-PLUS Solution Unicondylar Knee System is intended for use in unicompartmental degenerative arthritis, local osteonecrosis of the femoral condyle, light to medium unicompartmental destruction of the knee joint due to idiopathic and post-traumatic degenerative arthritis, traumatic unicompartmental bone and/or cartilage lesions. For use with bone cement only.
- 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.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUL 30 1999

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

Re: K982859  
Trade Name: UC-Plus Solution Unicondylar Knee System  
Regulatory Class: II  
Product Code: HRY  
Dated: May 4, 1999  
Received: May 5, 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 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.

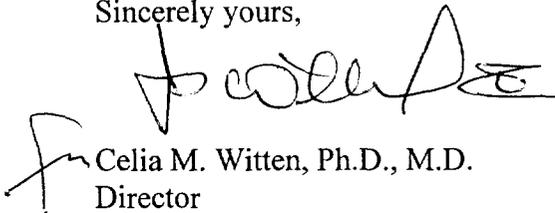
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

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,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is fluid and cursive, with a large initial "C" and "W".

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): \_\_\_\_\_

Device Name: UC-PLUS Solution Unicondylar Knee System

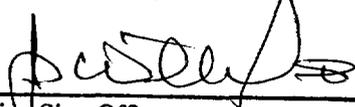
Indications for Use:

The UC-PLUS Solution Unicondylar Knee System is intended for use in unicompartmental degenerative arthritis, local osteonecrosis of the femoral condyle, light to medium unicompartmental destruction of the knee joint due to idiopathic and post-traumatic degenerative arthritis, traumatic unicompartmental bone and/or cartilage lesions. For use with bone cement only.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number     K982859    

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use \_\_\_\_\_

(Optional Format 1-2-96)