

NOV 25 1998

K 982447

Premarket Notification 510(k)
PLUS Bipolar Prosthesis CoCrMo
July 8, 1998

510(k) Summary of Safety and Effectiveness

September 11, 1998

Trade name: PLUS Bipolar Prosthesis CoCrMo

Common name: Bipolar Hip Joint Prosthesis

Classification name: Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis (87KWY)

Equivalence: Foundation Hip System, Bipolar Assembly, Encore Orthopedics, Austin, Texas (K953510).

Characteristics: The PLUS Bipolar Prosthesis CoCrMo is a one-piece hip joint prosthesis comprised of a CoCrMo shell, a polyethylene insert and polyethylene security ring. The advantages are 1) self-centering effect of the positive-excentric Bipolar prosthesis promotes the neutral position of the implant, 2) protects the acetabulum because the main articulation is between the implant femoral head and the Bipolar prosthesis, 3) optimum protection against the risk of dislocation with a built-in security ring, 4) the polyethylene insert is firmly fastened into the metal shell which prevents micromotion and polyethylene wear, 5) highly polished metal surface minimizes friction between implant and acetabulum.

Indications: The PLUS Bipolar Prosthesis CoCrMo is intended for use in arthroplasty therapy as a result of femoral neck fractures and is to be used in conjunction with standard femoral replacement implants.

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: None provided at this time.



NOV 25 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K982447
Trade Name: Plus Bipolar Prosthesis CoCrMo
Regulatory Class: II
Product Code: KWY
Dated: September 11, 1998
Received: September 14, 1998

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.

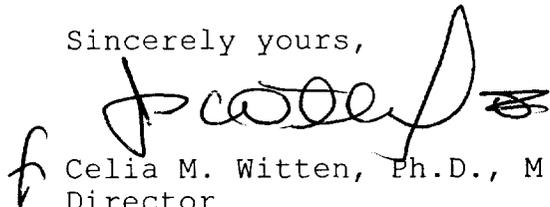
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

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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", with a stylized flourish at the end.

f 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): K982447

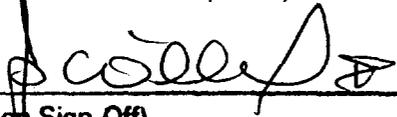
Device Name: Plus Bipolar Prosthesis CoCrMo

Indications For Use:

The Plus Bipolar Prosthesis CoCrMo is intended for use in arthroplasty therapy as a result of femoral neck fractures and is to be used in conjunction with standard femoral replacement implant. This device is intended for Cementless use only.

(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 K982447

Prescription Use Yes
(Per 21 CFR 801.109)

OR

Over-The-Counter Use No

(Optional Format 1-2-96)