

DEC 11 2000

Summary of Safety and Effectiveness Information Premarket Notification, Section 510(k)	EPF®-PLUS Cementless Press-Fit Acetabular Cup, K994146 October 6, 2000
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Regulatory Authority: Safe Medical Devices Act of 1990, 21 CFR 807.92

1. Device Name:

Trade Name: EPF®-PLUS Cementless Press-Fit Acetabular Cup

Common Name: Acetabular cup

Classification

Name: PROSTHESIS, HIP, SEMI-CONSTRAINED, METAL/POLYMER, UNCEMENTED

2. Establishment Name & Registration Number:

Name: PLUS ORTHOPEDICS

Number: 2086141

3. Classification:

No Code Section Reference Available.

Device Class: Class II

Classification Panel: Orthopaedic and Rehabilitation Devices Panel

Product Code: 87LWJ

4. Special Controls:

As a Class II medical device, guidance documents and special controls are in effect.

5. Equivalent Legally Marketed Device(s):

- PLUS EPF Acetabular Cup, Plus Orthopedics, **K972931**

The EPF®-PLUS Cementless Press-Fit Acetabular Cup is substantially equivalent as a result of the use of identical materials, identical indications for use and patient population, identical size offerings, identical instrumentation, identical production facilities and identical sterilization method. The only difference between the original and the modified device is the application of a flame sprayed plasma surface treatment. The characteristics of the surface treatment are not new and are commonly found on many similar orthopaedic implant devices.

6. Device Description:

The EPF®-PLUS Cementless Press-Fit Acetabular Cup is a surface treated titanium acetabular cup made from commercially pure titanium. The materials conform to national and international standards including ASTM F-136-98, ASTM F 67-95, gr. 4, F 639-93, ISO 5832-2. & ISO 5834 -1 & -2.

Indications for Use:

"The EPF®-PLUS Cementless Press-Fit Acetabular Cup is intended for all types of arthrosis, such as advanced destruction of the hip joint due to degenerative, post-traumatic or rheumatoid arthritis, fracture or avascular necrosis of the femoral head, sequelae of previous operations, such as internal fixation, joint reconstruction, arthrodesis, hemiarthroplasty or total hip replacement. The same considerations apply to acetabular revisions."

7. Applicant Name & Address:

PLUS ORTHOPEDIC
3550 General Atomics Court
Building # 15-100
San Diego, CA 92121
858.455.2400 tel - 858.455.2424 fax

8. Company Contact:

Mr. Hartmut Loch
PLUS ORTHOPEDIC
3550 General Atomics Court
Building # 15-100
San Diego, CA 92121
858.455.2400 tel - 858.455.2424 fax

9. Submission Correspondent:

Mr. David W. Schlerf
Buckman Company, Inc.
200 Gregory Lane, Suite C-100
Pleasant Hill, CA 94553-3389
925.356.2640 vox
925.356.2654 fax

10. Special Guidance Document Information:

Special Guidance documents are in effect for this device, including:

- Premarket Notification [510(k)] Applications for Orthopaedic Devices.
- Document for Testing Orthopaedic Implants With Modified Metallic Surfaces Apposing Bone or Bone Cement.

11. Storage, Packaging & Sterilization Information:

The *EPF®-PLUS Cementless Press-Fit Acetabular Cups* are supplied sterile. All implants are individually packaged & labeled and supplied in boxes for ease in shipping and storage. All packaging should be inspected on arrival for evidence of shipping damage. Any product for use in the operating room must be processed, opened, handled and placed into use following accepted operating room sterile technique. The product is terminally sterilized by an appropriate sterilization process exposure. Sterility Assurance Level (SAL) is at least 10^{-6} . Once opened, the product must be used or discarded. No attempt should be made at resterilization.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 11 2000

PLUS Orthopedics
c/o Mr. David W. Schlerf
Buckman Company, Inc.
200 Gregory Lane, Suite C-100
Pleasant Hill, California 94523-3389

Re: K994146
EPF®-PLUS Cementless Press-Fit Acetabular Cup
Product Code: LWJ, LZO
Regulatory Class: II
Dated: October 7, 2000
Received: October 17, 2000

Dear Mr. Schlerf:

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.

Page 2 - Mr. David W. Schlerf

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, Restorative and
Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number: **K994146**

Device Name(s):

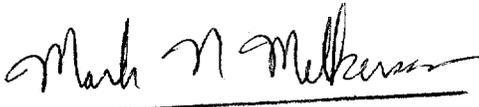
EPF®-PLUS Cementless Press-Fit Acetabular Cup

Intended Use:

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PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

for 

(Division Sign-Off)
Division of General Restorative Devices

510(k) Number

K994146

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____
(Optional format 1-2-96)