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510(k) Summary

SEP - 1 2006

SUBMITTED FOR:

Company Name: Portland Orthopaedics Limited
Address: Unit 3, 44 McCauley St
Matraville, NSW, 2036 Australia

Telephone: + 61-2-9666-8444
Fax: + 61-2-9666-8544

SUBMITTED BY: Elaine Duncan, M.S.M.E., RAC
President, Paladin Medical, Inc.

Address: Paladin Medical, Inc.
PO Box 560
Stillwater, MN 55082,
United States of America

Telephone: +1-715-549-6035
Fax: +1-715-549-5380

CONTACT PERSON: **Elaine Duncan**
DATE PREPARED: June 1, 2006

TRADE NAME: **Portland Ceramic (Biolox-Forte) Femoral Head**
COMMON NAME: Ceramic Femoral Head Prosthesis
DEVICE PROCODE & PANEL: Orthopaedics 87 LZO
REGULATION: **CFR § 888.3358, Class II**

DESCRIPTION of the DEVICE:
The Portland Portland Ceramic (Biolox-Forte) Femoral Head is provided as a single component. The device is manufactured from an Alumina Oxide (Biolox-Forte) and is available in various sizes. The internal bore of the femoral head is designed to taper lock (12/14) with the external male taper on a femoral hip stem providing articulation with a suitable acetabular module.

INDICATIONS FOR USE:
The Portland Ceramic (Biolox-Forte) Femoral Head has the following indications for use:

- The patient should be skeletally mature.
- The patient's condition should be due to one or more of the following:
  1. Osteoarthritis.
  2. Rheumatoid arthritis.

3. Tumor conditions involving the upper third of the femur or of the Acetabular.
4. Ankylosing spondylitis.
5. Psoriatic arthritis.
6. Old osteomyelitis - with a long infection-free period and a normal WBC, ESR and C-reactive protein.
7. Non union of femoral neck fracture or avascular necrosis of the femoral head.
8. Post-traumatic fracture/dislocation of the hip.
9. Revision of an unsuccessful arthrodesis with either poor positioning or pain in the hip, or where low back pain or knee pain is becoming disabling.
10. Revision of an unsuccessful cemented or un-cemented hip replacement, providing sufficient bone stock is present.
11. Revision of a previous unsuccessful femoral osteotomy, Girdlestone resection, cup arthroplasty or hemi arthroplasty.

SUBSTANTIAL EQUIVALENCE INFORMATION

The Portland Portland Ceramic (Biolox-Forte) Femoral Head described in this submission is substantially equivalent to ceramic femoral heads manufactured by DePuy, Exactech and Plus, based on similarities of design, intended use, material and manufacturing methods. As demonstrated by the test results and materials information, the differences in the Portland Ceramic (Biolox-Forte) Femoral Head do not raise any new issues of safety and effectiveness.

SUMMARY of TESTING:

Portland Orthopaedics, Ltd. has provided analytical and mechanical testing to demonstrate the substantial equivalence of and compliance to standards for the Ceramic (Biolox-Forte) Femoral Head.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 1 2006

Portland Orthopaedics, Ltd.
% Ms. Elaine Duncan, M.S.M.E., RAC
President, Paladin Medical, Inc.
P.O. Box 560
Stillwater, Minnesota 55082

Re: K061564
Trade/Device Name: Portland Ceramic (BIOLOX-Forte) Femoral Head
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: Class II
Product Code: LZO
Dated: June 1, 2006
Received: June 5, 2006

Dear Ms. Duncan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Bucher for

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K061564

Device Name: Portland Ceramic (Biolox-Forte) Femoral Head

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Mitchell

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K061564