OCT 7 - 2005

K051844 page 1 of 2

510(k) Summary

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.
PO Box 560
Stillwater, MN 55082
Telephone: 715-549-6035
Fax: 715-549-5380

CONTACT PERSON: **Elaine Duncan**
DATE PREPARED: July 5, 2005, revised September 26, 2005
TRADE NAME: Equator Plus™ Acetabular Cup System
COMMON NAME: Acetabular Cup System
DEVICE PROCODE & PANEL: : JDI, LWJ, MAY Orthopaedics 87

DESCRIPTION of the DEVICE:
The Equator Plus™ Acetabular Cup System is comprised of two units the first is a coated outer shell manufactured from titanium alloy (Ti-6Al-4V). The second unit is a ultra high molecular weight polyethylene (UHMWPE) liner force fitted into an outer cobalt chrome metal dome casing. The UHMWPE liner is provided as a single pre-assembled component. The Equator Plus™ Acetabular Cup System is to be used as part of a modulary total hip replacement system in a cementless application.

SUBSTANTIAL EQUIVALENCE INFORMATION
The Equator Plus™ Acetabular Cup System described in this submission is substantially equivalent to the predicate devices in the same classification and procode designation. Testing and materials qualification have demonstrated that the differences in the Equator Plus ™ Acetabular Cup System do not raise any new issues of safety and effectiveness. The Equator Plus™ Acetabular Cup System has been qualified for use with the Margron Hip Replacement System (cleared under K032641).

INDICATIONS FOR USE:
The Equator Plus™ Acetabular Cup System 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.

510(k) Summary-Continued

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.

SUMMARY of TESTING:

Portland Orthopaedics, Ltd. has provided analytical and mechanical testing to demonstrate the substantial equivalence of and compliance to standards for the Equator Plus™ Acetabular Cup System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 7 - 2005

Portland Orthopaedics Limited
c/o Ms. Elaine Duncan, M.S.M.E., RAC
President
Paladin Medical, Inc.
P.O. Box 560
Stillwater, Minnesota 55082

Re: K051844
Trade/Device Name: The Equator Plus™ Acetabular Cup System
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: II
Product Code: MAY, JDI, LWJ
Dated: September 26, 2005
Received: September 27, 2005

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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark Melkerson
Acting 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): K051844

Device Name: Equator Plus™ Acetabular Cup System

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  11. Revision of a previous unsuccessful femoral osteotomy, Girdlestone resection, cup arthroplasty or hemi arthroplasty.

Prescription Use ___X___ AND/OR Over-The-Counter Use No
(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)

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

510(k) Number K051844