K032641

JAN 2 0 2004

10. Summary of Safety and Effectiveness

Manufacturer:	Portland Orthopaedics Pty. Ltd. Unit 3, 44 McCauley Street Matraville, NSW, 2036 Australia
Contact:	David Sekel CEO, Portland Orthopaedics
Telephone Number: Fax Number:	011 (61) 2 9666 8444 011 (61) 2 9666 8544
Date Summary Prepared:	August 15, 2003
Product Trade Name:	MARGRON™ Hip Replacement System
Common Name:	Modular Femoral Hip Replacement System
Classification Name:	Hip joint/ceramic/polymer semi-constrained Cemented or nonporous uncemented prosthesis
Product Codes:	87 MEH & LPH – Device, Fixation, Proximal Femoral, Implant
Predicate Device:	MARGRON™ Hip Replacement System (K992158)

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Device Description:

The MARGRON™ hip replacement stem has been designed to be used in an uncemented mode in bone which is of good quality physiologically and which will heal quickly.

The MARGRON™ Femoral Stem is a modular prosthesis consisting of:

- A tapering stem cone with two different speed external threads and longitudinal derotation columns.
- A neck component which allows the optimum angle of anteversion to be selected after stem insertion.
- Precision milling and tapping is used to prepare the femur and stem insertion is by "screw home" rotation.
- A unique set of instruments have been designed to insert and extract the prosthesis.

Intended Use/Indications:

The MARGRON™ Hip Replacement System is intended for primary or revision restruction, without bone cement, of the femoral portion of a severely disabled and/or very painful hip joint, where radiographic evidence of sufficient sound bone is present.

The patient should be skeletally mature. The patient's condition should be due to one or more of the following:

- Osteoarthritis
- Rheumatoid arthritis
- Tumor conditions involving the upper third of the femur or the acetablum
- Ankylosing spondylitis
- Psoriatic arthritis
- Old osteomyelitis – with a long infection-free period and a normal WBC, ESR and C-reactive protein
- Non union of femoral neck fracture or avascular necrosis of the femoral head
- Post-traumatic fracture/dislocation of the hip
- 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
- Revision of an unsuccessful cemented or un-cemented hip replacement stem, providing sufficient bone stock is present
- Revision of a previous unsuccessful femoral osteotomy, Girdlestone resection, cup arthroplasty or hemi arthroplasty.

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Substantial Equivalence:

The MARGRON™ Hip Replacement System is substantially equivalent to the current MARGRON™ Hip Replacement System (K992815) in that:

- the intended use is the same
- the same operating principles is used
- the same final design configuration is incorporated
- both are labeled as sterile, single patient use
- both are packaged and labeled using the same materials and processes

Summary of Testing:

All materials used in the fabrication of this MARGRON™ Hip Replacement System were evaluated with the original design through physical testing (fatigue, torque and corrosion testing) and biocompatibility testing. It has been shown to be substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 0 2004

Mr. David Sekel
CEO
Portland Orthopaedics Pty. Ltd
Unit 3, 44 McCauley Street
Matraville, NSW, 2036
Australia

Re: K032641
Trade/Device Name: Margron™ Hip Replacement 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: MEH, LPH
Dated: December 18, 2003
Received: December 22, 2003

Dear Mr. Sekel:

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.

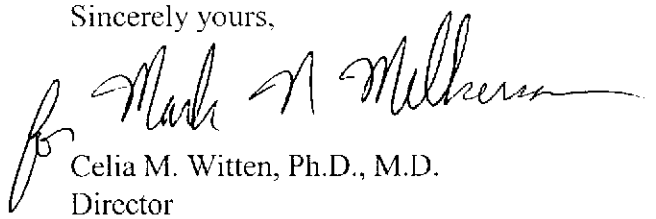
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4659. 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,



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 (if known): K032641

Device Name: MARGRON™ Hip Replacement System

Indications for Use:

The MARGRON™ Hip Replacement System is intended for primary or revision restruction, without bone cement, of the femoral portion of a severely disabled and/or very painful hip joint, where radiographic evidence of sufficient sound bone is present.

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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)

Prescription Use X **OR** _____ **Over-The-Counter Use**
(Per 21 CFR 801.109)

for Mark N Milhouse

Restorative
Devices

K032641

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

510(k) Number _____