FEB 7 2000

K 99-815

510(K)

~~14.0~~ Summary of Safety and Effectiveness

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Submitter Name and Address:	Portland Orthopaedics Pty. Ltd. Suite 3 Level 5 St. George Private Hospital 1 South Street Kogarah NSW 2217 Australia
Contact Person:	Dr. Ronald Sekel 011 (61) 2 9588 2121
Date Summary Prepared:	March 12, 1999
Proprietary Name:	Margron™ Hip Replacement System
Common Name:	Modular Femoral Hip Replacement System
Classification Name:	Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis. 21 CFR 888.3353
Product Codes:	87 ~~JDO~~ LPH/MEH - Device, Fixation, Proximal Femoral, Implant
Predicate Devices:	The Margron Hip is similar in design, materials and intended use to:

Manufacturer	Metagen	Biomet		Joint Medical/ J&J	Wright Medical Technology	S&N Richards
System Name	Modular Femoral Hip System (K980020)	Impact (K942027)	Mallory-Head (K921181)	S-ROM (K851422, K912713, K913231)	Infinity (K942115)	Modular Hip System (RMHS) (K912593)

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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
- Ankylosing spondylitis
- Psoriatic arthritis
- Old osteomyelitis - with a long infection free period and a normal WBC, C-Reactive protein and ESR
- 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 uncemented or 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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Materials

Materials for components of the Margron™ Hip Replacement System are implant grade materials.

Material Composition of the Components:

Stem	• Chrome Cobalt (Cr Co) • Calcium Phosphate Coating on upper half of stem
Neck	• Chrome Cobalt (Cr Co)

Chrome Cobalt (CrCo) per ASTM F-799-96

Mechanical Characteristics

The Margron Hip System has been evaluated by use of the fatigue, torque and corrosion tests. It has been shown to be substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 7 2000

Dr. Ronald Sekel
Director
Portland Orthopedics Pty. Ltd.
Suite 3 Level 5
St. George Private Hospital
1 South Street
Kogarah NSW 2217
Australia

Re: K992815
Trade Name: Margron Hip Replacement System
Regulatory Class: II
Product Code: MEH & LPH
Dated: November 27, 1999
Received: November 30, 1999

Dear Dr. Sekel:

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.

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 James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): New K992815

Device Name: Margron Hip Replacement System

Indication For Use:

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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)

(Division Sign-Off)

Div... ...storative Devices

510(k) Number K992815

Prescription Use ✓
(Per 21 CFR 801.109)