

510(k) Summary**Corentec Co., Ltd.****EAUM Total Knee System**

February 11, 2011

ADMINISTRATIVE INFORMATION

Manufacturer Name: Corentec Co., Ltd.
247 Giro-ri, Ipjang-myeon, Seobuk-Gu
Cheonan-si, Chungcheongnam-do, 331-822 South Korea
Telephone: +82-41-585-7114
Fax: +82-41-585-7113

Official Contact: J. S. Daniel
Project Manager, Regulatory Affairs

Representative/Consultant: Kevin A. Thomas, PhD
Floyd G. Larson
PaxMed International, LLC
11234 El Camino Real, Suite 200
San Diego, CA 92130
Telephone: +1 (858) 792-1235
Fax: +1 (858) 792-1236
Email: kthomas@paxmed.com
flarson@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name: EAUM Total Knee System
Common Name: Total Knee Prosthesis System

Classification Regulations: 21 CFR 888.3560, Class II
Product Code: JWH

Classification Panel: Orthopedic Products Panel
Reviewing Branch: Orthopedic Devices Branch

INTENDED USE

The EAUM Total Knee System is intended for use in total knee arthroplasty surgery for the following indications:

- Painful, disabling joint disease of the knee resulting from noninflammatory degenerative joint disease (including osteoarthritis, traumatic arthritis or avascular necrosis) or rheumatoid arthritis;
- Post-traumatic loss of knee joint configuration and function;
- Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability;
- Correction or revision of unsuccessful osteotomy, arthrodesis, or failure of previous arthroplasty procedure.

The EAUM Total Knee System is intended for cemented use only.

DEVICE DESCRIPTION

The EAUM Total Knee System is a patellofemoroltibial knee prosthesis system for cemented total knee arthroplasty. The EAUM Total Knee System consists of the following components: Femoral Components – eight (8) sizes in cruciate-retained (CR) and posterior stabilized (PS) designs, each for left and right sides; Tibial Baseplate (Tray) – nine (9) sizes for use on either the left or right side; Tibial Insert Components – nine (9) sizes for use on either the left or right side, with thicknesses ranging from 6 mm to 24 mm, provided in CR and PS designs; Patellar Components – five (5) sizes in two designs (dome and sombrero); and EAUM Total Knee Instrumentation for use with the system implant components. The components are manufactured from C-Cr-Mo alloy conforming to ASTM F75, *Standard Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implants (UNS R30075)* and UHMWPE conforming to ASTM F648 *Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants, Type 1 (GUR 1020)*. The components are sterilized by gamma irradiation.

EQUIVALENCE TO MARKETED DEVICES

Corentec Co., Ltd., submits the following information in this Premarket Notification to demonstrate that for the purposes of FDA's regulation of medical devices, the EAUM Total Knee System is substantially equivalent in indications and design principles to the following predicate devices, each of which has been determined by FDA to be substantially equivalent to pre-amendment devices:

- DePuy Orthopaedics, Inc., DePuy Sigma Knee Femoral Adapter, K060515;
- Howmedica Osteonics Corp., Triathlon Total Knee System, K053514; and
- Howmedica Osteonics Corp., Scorpio® NRG™ Knee System Components, K030978.

The EAUM Total Knee System and the predicate devices are all patellofemoroltibial knee prosthesis systems, intended for cemented total knee arthroplasty, and all have similar indications for use.

The EAUM Total Knee System and the predicate devices are made of the same materials, Co-Cr-Mo alloy (femoral components and tibial baseplate components) and UHMWPE (tibial insert components and patellar components), and all are provided sterilized by gamma irradiation.

The subject and predicate devices all have femoral components designed specifically for the right and left knees, provided in a range of sizes, and all include cruciate retaining (CR) and posterior stabilized (PS) designs. Similarly, the subject device and the predicate devices all include universal tibial baseplate (tray) components for use on either the left or right tibia, and all tibial baseplates incorporate a similar stabilizing keel design. All devices also include UHMWPE tibial inserts in CR and PS designs for use with the corresponding femoral components.

The EAUM Total Knee System and the predicate device components are similar in overall shape and design. The subject device and the predicate devices encompass a similar range of physical dimensions, including the AP and ML dimensions of the femoral and tibial baseplate components, the thickness of the tibial insert components, and the thickness and diameter of the patellar components.

Any differences in the technological characteristics between the subject and predicate devices do not raise new issues of safety or efficacy.

Performance testing was conducted to demonstrate substantial equivalence and included methods described in the following standards: ISO 7207-2, ASTM F2083, ISO 7207-1, ISO 21536, ISO 14879-1, ASTM F1800, ASTM F1223, ASTM F1814, and ISO 14243-1.

Overall, the EAUM Total Knee System has the following similarities to the predicate devices:

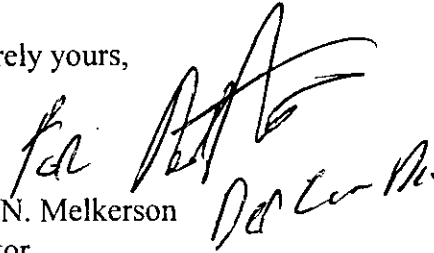
- has the same intended use,
- uses the same operating principles,
- incorporates the same basic designs,
- incorporates the same or very similar materials, and
- has similar packaging and is sterilized using the same materials and processes.

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



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

Enclosure

Indications for Use

510(k) Number: K110404

Device Name: EAUM Total Knee System

Indications for Use:

The EAUM Total Knee System is intended for use in total knee arthroplasty surgery for the following indications:

- Painful, disabling joint disease of the knee resulting from noninflammatory degenerative joint disease (including osteoarthritis, traumatic arthritis or avascular necrosis) or rheumatoid arthritis;
- Post-traumatic loss of knee joint configuration and function;
- Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability;
- Correction or revision of unsuccessful osteotomy, arthrodesis, or failure of previous arthroplasty procedure.

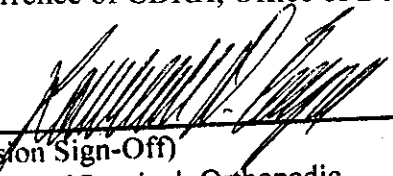
The EAUM Total Knee System is intended for cemented use only.

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)

Page 1 of __



 (Division Sign-Off)
 Division of Surgical, Orthopedic,
 and Restorative Devices

510(k) Number K110404