510(k) Summary

Corentec Co., Ltd.

EAUM Total Knee System

February 11, 2011

ADMINISTRATIVE INFORMATION

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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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Corentec Corporation, LTD.
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FEB 16 2012

Re: K110404
Trade/Device Name: EAUM Total Knee System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH
Dated: January 27, 2012
Received: January 30, 2012

Dear Mr. Thomas:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

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:

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Painful, disabling joint disease of the knee resulting from noninflammatory degenerative joint disease (including osteoarthritis, traumatic arthritis or avascular necrosis) or rheumatoid arthritis;

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

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

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

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