510(k) Summary

JUL 2 1 2011

Corentec Co., Ltd.

COREN® Total Hip System

K103431

July 14, 2011

ADMINISTRATIVE INFORMATION

Manufacturer Name:	Corentec Co., Ltd. 247 Giro-ri, Ipjang-myeon, Seobuk-Gu Cheonan-si, Chungchongnam-do, 331-822 South Korea Telephone: +82-41-585-7114 Fax: +82-41-585-7113
Official Contact:	J.S. Daniel Project Manager – QA/RA 11th Chungho Tower, 748-1 Banpo-1 Dong, Seocho Gu, Seoul, South Korea, 137-040 Telephone: +82-2-3445-5475 Fax: +82-2-3445-5497 Email: jsdaniel@corentec.com
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:	COREN® Total Hip System
Common Name:	Total Hip Prosthesis System
Classification Regulation:	21 CFR 888.3358, Class II
Product Codes:	LPH
Classification Panel:	Orthopedic Products Panel
Reviewing Branch:	Orthopedic Devices Branch

INTENDED USE

The COREN® Total Hip System is intended for use in total or partial hip arthroplasty and in primary or revision surgery for the following conditions:

a. Non-inflammatory degenerative joint disease, such as avascular necrosis, osteoarthritis, traumatic arthritis
b. Inflammatory degenerative joint disease, such as rheumatoid arthritis
c. Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques
d. Patients with failed previous surgery where pain, deformity, or dysfunction persists
e. Revision of previously failed total hip arthroplasty.

DEVICE DESCRIPTION

The COREN Total Hip System is a cementless, metal-on-polyethylene hip system for hip arthroplasty. It consists of the following components: Femoral stem – Modified BL Coren Stem; Femoral head – Coren Metal Head; Acetabular system – Coren U Cup, Coren PE Insert and Coren Bone Screw; and Coren THR Instrumentation. The components are manufactured from the following materials: Ti-6Al-4V alloy conforming to ASTM F136 *Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)*; Co-Cr-Mo alloy conforming to ASTM F1537 *Standard Specification for Wrought Cobalt-28-Chromium-6-Molybdenum Alloys for Surgical Implants (UNS R31537, UNS R31538, and UNS R31539)*; and ultra-high molecular weight polyethylene conforming to ASTM F648 *Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants*. COREN Total Hip System components are sterilized by gamma irradiation or ethylene oxide.

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 COREN® Total Hip 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:

Zimmer Austin, Inc., CLS™ Spotorno™ Stem, cleared under K042249;

Sulzer Orthopedics, Inc., CLS Varus/CLS 135 Stem, cleared under K010839;

Aesculap, Inc., Excia Total Hip System, cleared under K042344;

Wright Medical Technology, Inc., LINEAGE® A-CLASS™ Poly Liner, cleared under K052026;

Biomet, Inc., Metal on Metal Acetabular System, cleared under K993438; and

Biomet, Inc., M2a™ 32 mm Taper System, cleared under K003363.

The COREN Total Hip System Modified BL Coren Stem and the CLS™ Spotorno™ Stem (K042249) and the CLS Varus/CLS 135 Stem (K010839) are made of the same material, have the same grit-blasted surface finish, have the same neck angle and have similar overall geometries and ranges of sizes.

The COREN Total Hip System Coren U Cup and the Excia Total Hip System (K042344) are both hemispherical acetabular cup made of the same material and both have plasma-sprayed porous coatings with similar pore size, porosity and coating thickness. The subject and predicate acetabular cups also incorporate holes through the cup in similar positions and angulations for optional screw fixation, and both an internal taper mechanism for locking the UHMWPE insert to the cup.

The COREN Total Hip System and the LINEAGE® A-CLASS™ Poly Liner (K052026) both include UHMWPE inserts made of the same cross-linked material, encompassing a similar range of configurations, and both incorporate a taper mechanism for locking to the acetabular cup.

The COREN Total Hip System Coren Metal Head and the Metal on Metal Acetabular System (K993438) and M2a™ 32 mm Taper System (K003363) all include modular femoral heads made of the same material and a similar tapered interface to the femoral stem. The subject and predicate modular femoral heads all encompass a similar range of head sizes, neck lengths and femoral offsets, and all have similar surface finish and sphericity.

Any differences in technological characteristic 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 7206-4, ISO 7206-8, ASTM F543, ISO 14242-1, ISO 14242-2, ASTM F1820, ISO 7206-10, ISO 7206-9, ISO 7206-2, ASTM D638, ASTM F2183, ASTM F648, ASTM D3418, ASTM F2214, ASTM F2102, ASTM F2381, ASTM F1160, ASTM F1044, ASTM F1147, ASTM F1978, ASTM F2582, ISO 7206-6, and ISO 10993-7. The attachment strength between the UHMWPE liner and the acetabular shell was tested by measuring torque out and lever out strengths. Residual free radical content in crosslinked UHMWPE was assessed by electron spin resonance (ESR).

Overall, the COREN Total Hip 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 Co. Ltd
% Kevin Thomas, PhD
Vice President and Director of Regulatory Affairs
PaxMed International, LLC
11234 El Camino Real, Suite 200
San Diego, California 92130

JUL 2 1 2011

Re: K103431
Trade/Device Name: COREN® Total Hip System
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip Joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: LPH
Dated: June 15, 2011
Received: June 16, 2011

Dear Dr. 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,

for 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: K103431

Device Name: COREN® Total Hip System

Indications for Use:

The COREN® Total Hip System is intended for use in total or partial hip arthroplasty and in primary or revision surgery for the following conditions:

a. Non-inflammatory degenerative joint disease, such as avascular necrosis, osteoarthritis, traumatic arthritis

b. Inflammatory degenerative joint disease, such as rheumatoid arthritis

c. Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques

d. Patients with failed previous surgery where pain, deformity, or dysfunction persists

e. Revision of previously failed total hip arthroplasty.

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)

for M McMorrow

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

510(k) Number K103431