510(K) SUMMARY

SEP 10 2012

Corentec Co., Ltd.

Bencox Mirabo Cup System

Mar 25th, 2012

ADMINISTRATIVE INFORMATION

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DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	Bencox Mirabo Cup System
Common Name:	Acetabular Cup System
Classification Regulations:	21 CFR 888.3358
Class:	II
Product Codes:	LPH
Classification Panel:	Orthopedic Products Panel
Reviewing Branch:	Orthopedic Devices Branch

INTENDED USE

The intended use of the modified device [Bencox Mirabo Cup System] has not changed as a result of the modification of the predicate device [Bencox (Coren) Total Hip System], cleared under K103431.

The Bencox Mirabo Cup System is intended for use in total hip arthroplasty 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 Bencox Mirabo Cup System is part of a modular system for use in total hip replacement. The acetabular component is provided as two separate units, a porous coated non hemispherical outer shell manufactured from titanium alloy (Ti-6AI-4V) and a liner manufactured from highly crosslinked ultra high molecular weight polyethylene (UHMWPE), which locks into the outer shell. The liner component articulates with a femoral head of an appropriate diameter.

The Acetabular system consists of Bencox Mirabo Cup, Bencox Mirabo PE Inserts (Standard & Elevated), Bencox Bone Screw, Dome hole & Screw Hole Plugs; and Bencox 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)*; 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.* The acetabular cup is sterilized by gamma irradiation and acetabular liner is sterilized by ethylene oxide, same as its predicate device cleared under K103431.

SUBSTANTIAL EQUIVALENCE

Bencox Mirabo Cup 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, as below,

- **Corentec Co., Ltd.**, Coren Total Hip System (*now renamed as Bencox Total Hip System*) cleared under K103431
- **DePuy Orthopedics Inc.**, Pinnacle Acetabular System cleared under K000306

PERFORMANCE DATA

Performance testing was carried out to demonstrate substantial equivalence and included methods described in the following standards: ISO 14242, ASTM F1820 and ASTM F2582. Mechanical testing of the subject device consisted of wear, liner torsion & lever out, push out and impingement testing. The acetabular cup system performed either similar or better than the predicate devices.

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

Overall, the Bencox Mirabo Cup has similarities to the predicate devices with the same intended use, same fundamental scientific technology, same operating principles, same materials and are supplied Sterile.

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

SEP 10 2012

Corentec Company, Limited
% Mr. J.S. Daniel
Project Manager, Regulatory Affairs and Quality Assurance
8th Chungho Tower, 748-1 Banpo 1 Dong
Seocho Gu, Seoul, Korea 137-040

Re: K120924
Trade/Device Name: BENCOX MIRABO CUP SYSTEM
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coat-ed uncemented prosthesis
Regulatory Class: Class II
Product Code: LPH
Dated: August 08, 2012
Received: August 13, 2012

Dear Mr. Daniel:

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

K 120924 (1/1)

INDICATIONS FOR USE

510(k) Number (if known):

Device Name: BENCOX MIRABO CUP SYSTEM

The Bencox Mirabo Cup System is intended for use in total hip arthroplasty 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 (Per 21 CFR 801 Subpart D) AND / OR Over-The Counter Use: ____ (Per 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 (Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K 120924