October 17, 2017

Corentec Co., Ltd.
J.S. Daniel
Associate Director- Global RA/QA
8F Chungho Tower, 483, Gangnam-daero,
Seocho Gu, Seoul, South Korea-06541

Re: K172806
Trade/Device Name: Bencox Mirabo Cup 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: September 15, 2017
Received: September 18, 2017

Dear J.S. 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 contact the Division of Industry and Consumer Education (DICE) 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education (DICE) 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,

Katherine D. Kavlock -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K172806

Device Name

Bencox Mirabo Cup System

Indications for Use *(Describe)*

Bencox Mirabo Cup System of Bencox Total Hip System is intended for Cementless use in partial or 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 trochantric 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

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) SUMMARY
Corentec Co., Ltd.
Bencox Mirabo Cup System
15th Sept., 2017

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
Regulatory Class:	II
Product Codes:	LPH
Classification Panel:	Orthopedic Products Panel

INDICATIONS FOR USE

Bencox Mirabo Cup System of Bencox Hip Replacement System is intended for cementless use in partial or 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 trochantric 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

1) Bencox Mirabo Cup System: (Sterile)

The Bencox Mirabo Cup System is a Cementless hip acetabular system (*Metal on Poly Liner or Ceramic on Poly Liner*) for hip arthroplasty. This submission consists of the following components:

- Acetabular Cup - Bencox Mirabo Cup
- Acetabular Liner - Bencox Mirabo PE Liner

Acetabular Cup: Bencox Mirabo Cup

The Bencox Mirabo Cup Spec. Inclusion is similar to Bencox Mirabo Cup cleared under K162127 & K120924 with respect to material – Titanium alloy (ASTM F136), coating with pure Titanium powder (ASTM F1580), design, locking system, manufacturing, packaging and sterilization. This submission is only for the inclusion of specification of acetabular cups with external diameter 44 mm.

Acetabular Liner: Bencox Mirabo PE Liner

The Bencox Mirabo PE Liner specification inclusion is similar to Bencox Mirabo PE Liner cleared under K162127 & K150007, with respect to material, *conforming to ASTM F648, Type 2 (GUR 1050),* and irradiated with average dose of 10.0 Mrad of gamma radiation, design, locking system, manufacturing, packaging and sterilization. This submission is only for the inclusion of specification of Liners with head size, 28/35 & 32/39 mm.

2) Bencox Hip Replacement System Instrumentation (Non Sterile)

Bencox Hip Replacement System Instrumentation is a set of accessories to be used with Bencox Hip Implants. The parts of the instruments are made of stainless steel and/or polymers and/or silicon and cleared for use in previous premarket notifications of Corentec. Bencox Hip System Instrumentation to be used with Bencox Mirabo Cup System is same with Instrumentation cleared under K162127 and K150007 & K120924 along with the inclusion of instruments specific to Bencox Mirabo Cup System components included in this submission.

SUBSTANTIAL EQUIVALENCE

Bencox Mirabo Cup System is similar to the 510(k) cleared devices as mentioned below with respect to indications, design, specifications, operating principles and material.

Predicate Category	Manufacturer	Trade Name	510(k)
Primary	Corentec	Bencox Mirabo Cup System	K162127
		Bencox Mirabo PE Liner	
Additional	Corentec	Bencox Mirabo PE Liner	K150007
		Bencox Mirabo Cup System	K120924
	DePuy	Pinnacle Acetabular System *with ALTRX Liner*	K000306 & K062148

The subject devices Bencox Mirabo Cup System and the Bencox Mirabo Cup (K162127 & K120924) has acetabular cups 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 liner to the cup.

The subject devices Bencox Mirabo Cup System and the Bencox Mirabo PE Liner (K162127 & K150007) is made of the same material, UHMWPE and cross-linked to 10 Mrad. Both incorporate a taper mechanism for locking to the acetabular cup and have standard and elevated types of Inserts Type A with angles 10°, 15°. The Bencox Mirabo Cup system has similar dimensional specification with additional predicate device, Pinnacle Acetabular System, K000306 & AltrX Liner K062148.

PERFORMANCE DATA

Bencox Mirabo Cup System was subjected to a series of testing protocols to document the performance of the components and to demonstrate substantial equivalence. Non-clinical testing and analysis included *Wear Testing (ISO 14242-1), Liner Torsion (ASTM F1820 Torque Out Disassembly) & Pull out Testing (ASTM F1820 Offset Pull out disassembly), Push out (ASTM F1820 Axial Disassembly), Impingement Testing (ASTM F2582), Range of Motion Testing (ISO 21535) & Endotoxin Testing (ANSI/AAMI ST72)* for Acetabular Cup and Liner and Risk Management (ISO 14971). The results of this testing/analysis showed that the subject devices are expected to be safe and effective for the proposed indications and are substantially equivalent to the predicate devices.

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STERILIZATION & PACKAGING

For sterile metal component Bencox Mirabo Cup, following to gamma sterilization, packaging was subjected to sterile barrier testing to validate a shelf life of 5 years as per ISO & ASTM standards which confirms the stability and effectiveness of packaging of the sterilized product during the shelf-life, by evaluating changes by accelerated aging, as per ASTM F1980. Sterilization validation as per *ISO 11137–1 & 2 Sterilization of health care products – Radiation* ensures sterility of the components for a SAL of 10^{-6}.

For the sterile UHMWPE components - Bencox Mirabo PE Insert, following to EtO sterilization process, packaging was subjected to sterile barrier testing to validate a shelf life of 5 years as per ISO & ASTM standards which confirms the stability and effectiveness of packaging of the sterilized product during the shelf-life, by evaluating changes by accelerated aging, as per ASTM F1980. Sterilization validation as per *ISO 11135-1, Sterilization of health care products - Ethylene oxide - Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices* ensures sterility of the components for a SAL of 10^{-6}. EtO Residuals were determined according to ISO 10993-7, Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals. The test results are within the limits specified in ISO 10993-7.

Sterile Bencox Mirabo Cup System components have same shelf life of 5 years, similar to other cleared sterile devices of Corentec**.** The non sterile Bencox hip replacement system instrumentation used in the surgery must be sterilized by the hospital, prior to use, as mentioned in the IFU.

CONCLUSION

Overall Bencox Mirabo Cup System components included in this PMN is similar to the identified primary predicate device and additional predicates. The identified minor differences between the subject devices and predicate(s) do not constitute a new intended use and the minor differences in the technological characteristics do not affect or raise new queries of safety and effectiveness based on successful performance testing conforming to recognized performance standards for hip replacement devices and has been adequately addressed in this premarket notification.

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