May 18, 2022

Corentec Co.,Ltd.
Yoorim Bae
RA Manager
12, Yeongsanhong 1-gil, Ipjang-Myeon, Seobuk-Gu
Cheonan-si, Chungcheongnam-do 31056
Republic of Korea

Re: K220468
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, LZO
Dated: May 16, 2022
Received: May 16, 2022

Dear Yoorim Bae:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Limin Sun, Ph.D.
Acting Assistant Director
DHT6A: Division of Joint
Arthroplasty Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K220468

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

(As required by 21 CFR 807.92)

Date: February 15, 2022

Administrative Information

Manufacturer: Corentec Co., Ltd.
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Device Information

Trade or Proprietary Name:	BENCOX Mirabo Cup system
Common Name:	Acetabular Cup Prosthesis, Acetabular Liner Prosthesis
Classification Name:	Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Class:	II
Classification panel:	87 Orthopedics
Regulation:	21CFR888.3358 21CFR888.3353
Product Code(s):	LPH, LZO

Legally Marketed Device(s) to Which Equivalence is Claimed

Predicate Devices		Manufacturer	510(k) number
Primary Predicate	BENCOX Mirabo Cup System	Corentec Co.,Ltd	K120924
Additional Predicate	BENCOX Mirabo PE Liner		K150007
	BENCOX Mirabo Cup Line extension		K162127 K172806
	BENCOX Mirabo Cup Multi-hole		K182221
	ConforMIS BeneFIT Hip system	ConforMIS, Inc.	K190904
	ZIMMER CONTINUUM ACETABULAR SYSTEM, ZIMMER TRILOGY IT ACETABULAR SYSTEM	ZIMMER, INC.	K091508

	E-XLPE Acetabular Components and U-Motion II Acetabular Cup	United Orthopedic Corporation	K172833

Reason for 510(k) Submission
The purpose of this submission is to include additional sizes for Cups and Liners to the previously cleared hip system.

Device Description
The Bencox Mirabo Cup System is a Cementless hip acetabular system (Poly Liner) intended to be used with femoral components including either metal or ceramic heads and femoral stems to form a total hip system for hip arthroplasty. This submission consists of the following line extension 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 50 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 Liner with head size, 28/42, 32/42, 36/42 mm.

Indications for Use

BENCOX Mirabo Cup System of BENCOX Total Hip System is intended for Cementless 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

Summary of Technological Characteristics
The subject liners and acetabular shells are manufactured from the same materials and have the same locking mechanism and feature. The liners and shells are thinner than the previously cleared components. However, they are not thinner than the additional predicates.

Non-Clinical Testing

This submission references mechanical testing results and engineering analysis for:

- Wear Testing as per ISO 14242-1
- Liner Torsion as per ASTM F1820
- Pull out Testing as per ASTM F1820
- Push out Testing as per ASTM F1820
- Impingement as per ASTM F2582
- Cup deformation as per ISO 7206-12
- Acetabular cup fatigue as per ASTM F3090-20
- Range of Motion as per ISO21535
- Biocompatibility

Pyrogen testing was conducted in accordance with USP<161>, USP<85>, and ANSI/AAMI ST72 to ensure the proposed BENCOX Mirabo Cup System meets recommended limits per *FDA's Guidance Document submission and Review of Sterility Information in Premarket (510(k)) Submission for Devices Labeled as Sterile.*

Bacterial endotoxin testing (BET) as specified in ANSI/AAMI ST72:2011 was used for pyrogenicity testing to achieve an Endotoxin limit of < 20EU/Device.

Substantial Equivalence Conclusion

Based upon a comparison of intended use, materials, summary of technological characteristics, and preclinical testing, the BENCOX Mirabo Cup System is substantially equivalent to the predicate devices identified in this premarket notification.