February 27, 2023

Corentec Co., Ltd.
Songe Kang
RA Associate
12, Yeongsanhong 1-gil, Ipjang-Myeon, Seobuk-Gu
Cheonan-si, Chungcheongnam-do 31056
Republic of Korea

Re: K223223
Trade/Device Name: BENCOX Mirabo Z Cup Cortinium
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: February 21, 2023
Received: February 21, 2023

Dear Songe Kang:

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 -S

Limin Sun, Ph.D.
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)*

K223223

Device Name
BENCOX Mirabo Z Cup Cortinium

Indications for Use *(Describe)*

BENCOX Mirabo Z Cup Cortinium 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 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

(As required by 21 CFR 807.92)

Date: October 14, 2022

Administrative Information

Manufacturer: Corentec Co., Ltd.
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Device Information

Trade or Proprietary Name:	BENCOX Mirabo Z Cup Cortinium
Common Name:	Acetabular Cup Prosthesis
Classification Name:	Hip Joint Metal/Polymer/Metal Semi-Constrained Porous-Coated Uncemented Prosthesis. (21CFR888.3358)
Class:	II
Product Code(s):	LPH

Predicate Devices

Primary predicate:	BENCOX Mirabo Z cup Cortinium (K210614)
Additional predicates:	BENCOX Mirabo Cup System (K120924, K162127, K172806, K220468)

Reason for 510(K) Submission

The purpose of this submission is to include an additional size 50mm diameter acetabular cup to the previously cleared hip system.

Device Description

The subject BENCOX Mirabo Z cup Cortinium shares key design features, materials, Indications for Use statements, geometry, and compatibility with other Corentec acetabular components marketed under the brand names BENCOX Mirabo Cup System and BENCOX Mirabo Z Cup Cortinium.

The BENCOX Mirabo Z cup Cortinium is similar to the predicate devices BENCOX Mirabo Z Cup Cortinium cleared under K210614 and Bencox Mirabo Cups cleared under K220468, K172806, K162127, K120924 with respect to material – Titanium alloy (ASTM F136), and coated by pure titanium powder (ASTM F1580) through an additive manufacturing process, design, locking system, manufacturing (without coating processes), packaging and sterilization. This submission is only for the inclusion of specification of BENCOX Mirabo Z Cup Cortinium with external diameter 50mm.

The manufacturing process including additive manufacturing is identical to the predicate.
The subject 50mm acetabular shell is thinner than the predicate 50mm shells but it is not thinner than other sized shells in the predicate submission. Otherwise, the geometry of the features is identical to the predicate.
The subject devices operate using the same fundamental scientific technology, have the same intended use and design features, employ the same materials of construction, are offered in the same product size scopes, and are implanted using a similar surgical technique and the same or similar instrumentation to legally marketed device cleared under K120924, K162127, K172806, K220468 and K210614.

Indications for Use

BENCOX Mirabo Z Cup Cortinium 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
Device Comparisons and performance testing indicate that BENCOX Mirabo Z Cup Cortinium is substantially equivalent to the predicates in terms of intended use, indications, design, materials, performance characteristics and operational principles.

Non-Clinical Testing

The Corentec Co., Ltd. has evaluated the subject BENCOX Mirabo Z Cup Cortinium to demonstrate substantial equivalence to the predicate devices BENCOX Mirabo Z Cup Cortinium cleared under K210614 and Bencox Mirabo Cups cleared under K220468, K172806, K162127, K120924, and determined that the subject devices do not represent a new worst case.

- Wear Testing as per ISO 14242-1 and 14242-2
- Cup Deformation as per ISO 7206-12
- Shell Fatigue Testing as per ASTM F3090
- Impingement Testing as per ASTM F2582
- Push out Testing as per ASTM F1820
- Lever out Testing as per ASTM F1820
- Offset Pull out Testing as per ASTM F1820
- Torque out Testing as per ASTM F1820
- Range of Motion as per ISO 21535
- Biocompatibility risk assessment and testing

Pyrogen testing was conducted in accordance with USP<161>, USP<85>, and ANSI/AAMI ST72 to ensure the proposed BENCOX Mirabo Z Cup Cortinium 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 non-clinical testing, the BENCOX Mirabo Z Cup Cortinium is substantially equivalent to the predicate devices identified in this premarket notification.