May 24, 2022

Corentec Co.,Ltd.
Yoorim Bae
RA specialist
12, Yeongsanhong 1-gil, Ipjang-myeon, Seobuk-gu
Cheonan-si, Chungcheongnam-do 31056
Republic of Korea

Re: K210614
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: May 18, 2022
Received: May 18, 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)*
K210614

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.

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

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510(k) SUMMARY
Corentec Co., Ltd.

BENCOX Mirabo Z Cup Cortinium
of BENCOX Total Hip System
May 24, 2022

ADMINISTRATIVE INFORMATION

Manufacturer: Corentec Co., Ltd.
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DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	BENCOX Mirabo Z Cup Cortinium
Common Name:	Acetabular Cup Prosthesis
Classification Regulations:	21 CFR 888.3358 Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis.
Regulatory Class:	Class II
Product Codes:	LPH
Classification Panel:	Orthopedic Products Panel

Legally Marketed Predicate Devices to Which Substantial Equivalence is Claimed:
Primary predicate:

510(k) Number	Trade or Proprietary Model Name	Manufacturer
K120924	BENCOX Mirabo Cup System	Corentec Co.,Ltd.

Additional Predicates Supporting Substantial Equivalence:

510(k) Number	Trade or Proprietary Model Name	Manufacturer
K000306 & K093646	Pinnacle Acetabular System with ALTRX Liner	DePuy Orthopaedics, Inc.
K150790	REDAPT Porous Acetabular Shell and Cemented Liner	Smith & Nephew Inc.
K061253, K070756	REFLECTION 3 ACETABULAR SYSTEM	Smith & Nephew Inc.
K182502	Exactech® Alteon® Acetabular Cup System	Exactech, Inc.
K162127	BENCOX Mirabo Cup Line extension	Corentec Co.,Ltd.
K172806	BENCOX Mirabo Cup Line extension	Corentec Co.,Ltd.
K182221	BENCOX Mirabo Cup Multi hole	Corentec Co.,Ltd.

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

DEVICE DESCRIPTION

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.

The BENCOX Mirabo Z Cup Cortinium is a porous coated non hemispherical outer shell made of Ti-6Al-4V alloy (ASTM F136) via machining processes and coated by pure titanium powder (ASTM F1580) through an additive manufacturing process. The device design allows for the cementless use of cross-linked polyethylene liners into the shell and incorporates screw holes for fixation.

The subject devices operate using the same fundamental scientific technology, have the same intended use and design features, employ the same materials of constructions, 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, and K182221. The only modifications subject by this submission are the titanium porous coating process of acetabular shell.

SUMMARY of TECHNOLOGICAL CHARACTERISTICS

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

NONCLINICAL TESTING DESCRIPTION

Nonclinical bench testing was performed to evaluate and demonstrate the substantial equivalence of the subject BENCOX Mirabo Z Cup Cortinium to its legally marketed predicate devices.

- Cup Fatigue Testing per ASTM F3090-20
- Cup Deformation Testing per ISO 7206-12
- Porous Structure Characterization (Composition, Trace element, Microstructure, Mean void intercept length, Porosity, Shear mechanical properties, Tensile mechanical properties, Abrasion resistance, Roughness) per ASTM E112, ASTM F1854, DIN EN ISO 25178, ASTM F1147, ASTM F1044, ASTM F1160, ASTM F1978

Predicate nonclinical test results were leveraged to support the subject device via engineering analysis/ justification.

- Axial Pushout, Offset Pullout, and Torque-out per ASTM F1820
- Impingement per ASTM F2582
- Range of Motion (ROM) per ISO21535
- Wear testing per ISO 14242-1

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.

BIOCOMPATIBILITY
The intended patient contact and materials used in the subject implant devices are identical to the predicate devices (K120924).

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.