March 16, 2023

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

Re: K223828
Trade/Device Name: BENCOX Delta Option Heads
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip Joint Metal/Ceramic/Polymer Semi-Constrained Cemented Or Nonporous Uncemented Prosthesis
Regulatory Class: Class II
Product Code: LZO, KWY
Dated: December 12, 2022
Received: December 21, 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 -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)*
K223828

Device Name
BENCOX Delta Option Heads

Indications for Use *(Describe)*
BENCOX Delta Option Heads of BENCOX Total Hip System is intended for Cementless use in total or partial 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

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: March 15, 2023

ADMINISTRATIVE INFORMATION

Manufacturer:	Corentec Co., Ltd. 12, Yeongsanhong 1-gil, Ipjang-Myeon, Seobuk-Gu Cheonan-si, Chungchongnam-do, Rep. of Korea -31056 Telephone: +82-41-585-7114; Fax: +82-41-585-7113
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DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	BENCOX Delta Option Heads
Common Name:	Femoral Head Prosthesis
Regulation and Classification Name:	21 CFR 888.3353 Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class:	Class II
Product Codes:	LZO, KWY
Classification Panel:	Orthopedic Products Panel
Reviewing Branch:	Orthopedic Devices Branch

Legally Marketed Predicate Devices to Which Substantial Equivalence is Claimed:

Primary Devices Supporting Substantial Equivalence:

510(k) Number	Trade or Proprietary Model Name	Manufacturer
K192416	BIOLOX Delta Ceramic Femoral Heads, BIOLOX Option Ceramic Femoral Head System	Zimmer GmbH

Reference Devices Supporting Substantial Equivalence:

510(k) Number	Trade or Proprietary Model Name	Manufacturer
K121665	BENCOX Forte & BENCOX Delta	Corentec Co., Ltd.
K173776	BIOLOX delta Option and Extra-long Heads	MicroPort Orthopedics Inc.
K103012	Exactech BIOLOX®Delta Femoral Heads and BIOLOX® Option Femoral Heads and Adapters	Exactech, Inc.

Indications For Use

BENCOX Delta Option Heads of BENCOX Total Hip System is intended for Cementless use in total or partial 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

Purpose and Device Description

The BENCOX Delta Option Head consists of a delta ball head and a titanium sleeve (Ti6Al4V). The ball heads are made of the BIOLOX® *delta* ceramic material, which is a high-purity alumina composite material according to ISO 6474-2 Type X, and come in various outer diameters.

The ceramic BIOLOX® *delta* ball head is assembled with the corresponding titanium sleeve and is then placed over the titanium alloy tapers of an in-situ hip stem prosthesis. The titanium sleeve has an inner taper which fits the dimensions of a metallic hip stem prosthesis, and the BIOLOX® *delta* ball head has a taper which fits to the dimensions of the outer diameter of the titanium sleeve.

The design features and materials of the subject device, BENCOX Delta Option head are substantially equivalent to BIOLOX® *delta* Option devices cleared under K192683 and K173776 since the subject device is supplied by CeramTec.

Summary of Technological Characteristics

Device Comparisons and performance testing indicate that the BENCOX Delta Option Heads are substantially equivalent to the predicates in terms of intended use, indications, design, materials, performance characteristics and operational principles.

Non-Clinical Studies

The following tests were performed on the BENCOX Delta Option Heads to demonstrate substantial equivalence of safety and efficacy with the predicate devices:

- Burst Testing
- Fatigue Testing
- Post-fatigue Burst Testing
- Pull-off Testing
- Torque-out Testing
- Range of Motion
- Corrosion Testing and Assessment

Pyrogen testing was conducted in accordance with USP<161>, USP<85>, and ANSI/AAMI ST72 to ensure the proposed BENCOX Delta Option Heads meet 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.

Clinical Testing: Clinical testing was not required

Substantial Equivalence Conclusion

Based upon a comparison of intended use, materials, summary of technological characteristics, and preclinical testing, the BENCOX Delta Option Heads are substantially equivalent to the predicate devices identified in this premarket notification.