July 14, 2021

Corentec Co., Ltd.
Sungwon Yang
Qmr
12, Yeongsanhong 1-gil, Ipjang-Myeon, Seobuk Gu
Cheonan-si, Chungchongnam-do 31056
Korea, South

Re: K211866
Trade/Device Name: BENCOX THR 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, KWY
Dated: June 11, 2021
Received: June 16, 2021

Dear Sungwon Yang:

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,

for

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)*
K211866

Device Name
BENC0X THR System

Indications for Use *(Describe)*

BENC0X Total Hip System is intended for cementless use in total or partial hip arthroplasty in primary or revision surgery for the following conditions:

- non-inflammatory degenerative joint disease, such as avascular necrosis, osteoarthritis, traumatic arthritis;
- Inflammatory degenerative joint disease, such as rheumatoid arthritis;
- Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques;
- patients with failed previous surgery where pain, deformity, or dysfunction persists;
- 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.

510(K) SUMMARY

Corentec Co.,Ltd.

BENCOX THR System

June 11th, 2021

ADMINISTRATIVE INFORMATION

Manufacturer: Corentec Co., Ltd.
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Cheonan-si, Chungchongnam-do, South Korea -31056
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Ph: +82-41-410-7117 (Direct) ; Fax: +82-41-585-7113
Email: sr.kim@corentec.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	BENCOX THR System
Common Name:	Total Hip Joint Replacement Prosthesis
Classification Regulations:	21 CFR 888.3358, 888.3353, 888.3390
Class:	II
Product Codes:	LPH, LZO, KWY
Classification Panel:	Orthopedic Products Panel
Reviewing Branch:	Orthopedic Devices Branch

INDICATIONS FOR USE

The Indications for Use of the added specification has not changed as a result of the modification of the predicate device cleared under BENCOX THR System, K112019 & K150007 & K162127.

BENCOX Total Hip System is intended for cementless use in total or partial hip arthroplasty in primary or revision surgery for the following conditions:

- non-inflammatory degenerative joint disease, such as avascular necrosis, osteoarthritis, traumatic arthritis;
- Inflammatory degenerative joint disease, such as rheumatoid arthritis;
- Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques;
- patients with failed previous surgery where pain, deformity, or dysfunction persists;
- revision of previously failed total hip arthroplasty.

DEVICE DESCRIPTION

The Additional components being added to the BENCOX THR System are:
- Instrumentation (Head trial, Bencox Hybrid PE Liner Trial – STD/ELV, Bencox Mirabo PE Liner Trial – STD/ELV, Shell Trial, Bipolar Cup Trial, Bipolar Cup Trial Ring, Head Impacting Part, Liner Impacting Part)

The Bencox Hip Instrumentation is a set of accessories to be used with Bencox Hip Implants. The instruments are designed to be simple, conventional, and accurate and all parts of which are used for their respective procedures by qualified orthopedic surgeons. The parts of the instruments are made of Propylux and/or SUS along with colorants which are biocompatible and used in medical industry for decades and cleared for use in previous premarket notifications of Corentec.

The Trials are used to match the different anatomical structures of the hip joint and the Impacting Parts are used to combine the components together. These instruments are reusable devices that must be sterilized prior to use.

The trials and impacting parts of this submission are made of Propylux and/or SUS conforming to ASTM D4101: Standard Classification System and Basis for Specification for Polypropylene Injection and Extrusion Materials, and ASTM F899:
Standard Specification for Wrought Stainless Steels for Surgical Instruments, respectively.

Substantial Equivalence
BENCOX THR System is substantially equivalent in indications and design principles to the following predicate devices, each of which has been determined by FDA to be substantially equivalent to pre-amendment devices:

Substantially equivalent products for BENCOX THR System are as follows,

Legally Marketed Predicate Devices to Which Substantial Equivalence is Claimed:

510(k) Number	Trade or Proprietary Model Name	Manufacturer
K162127	Bencox M Stem Lat. Offset & Mirabo Cup System	Corentec Co. Ltd

Reference Devices Supporting Substantial Equivalence:

510(k) Number	Trade or Proprietary Model Name	Manufacturer
K112019	BENCOX Bipolar Cup System	Corentec Co. Ltd
K150007	Modified Bencox Mirabo Hip System	Corentec Co. Ltd

Summary of Technological Characteristics:

BENCOX THR System additional instrumentations performed either similar comparable predicate devices and are as safe and effective as predicate device. Any differences in

technological characteristic between the subject and predicate devices do not raise new issues of safety or efficacy. At a high level, BENCOX THR System has the following similarities to the predicate devices:

- has the same intended use,
- has the same indications for use,
- has the same operating principles,
- has the same conditions of use,
- incorporates the same basic design
- has the similar size, and
- is supplied non-sterile

Non-Clinical Testing

The following non-clinical laboratory testing and/or engineering analysis were performed to determine substantial equivalence:

- Dimensions measurement testing

The designs, dimensions and function of additional instruments are similar with predicate devices under K162127. Additional performance testing is unnecessary since the trial is not implanted.

Clinical Testing

Clinical testing for BENCOX THR System Instrumentation were not required as a basis for substantial equivalence.

STERILIZATION & PACKAGING

BENCOX THR System Instrumentation are supplied non-sterile and cited predicate devices are non-sterile.

CONCLUSION

Corentec Co., Ltd. believes that the subject devices are substantially equivalent to the legally marketed predicate device based on intended use, technology, geometry as well as the non-clinical testing.