Corentec Co., Ltd
J.S Daniel
Associate Director-Global RA/QA/CA
8F Chungho Tower, 483, Gangnam-daero, Seocho Gu
Seoul, 06541 Kr

April 1, 2019

Re: K182221
Trade/Device Name: Bencox Mirabo Cup Multi Hole
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: March 5, 2019
Received: March 7, 2019

Dear J.S Daniel:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Daniel S. Ramsey -S
2019.04.01 15:29:25 -04'00'

FOR Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K182221

Device Name

Bencox Mirabo Cup Multi Hole

Indications for Use *(Describe)*

Bencox Mirabo Cup Multi Hole 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.

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K182221

510(K) SUMMARY
Corentec Co., Ltd.
Bencox Mirabo Cup Multi Hole
30th Mar, 2019

ADMINISTRATIVE INFORMATION

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DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	Bencox Mirabo Cup Multi Hole
Common Name:	Acetabular Cup System
Classification Regulations:	21 CFR 888.3358
Regulatory Class:	II
Product Codes:	LPH
Classification Panel:	Orthopedic Products Panel

INDICATIONS FOR USE

Bencox Mirabo Cup System of Bencox Hip Replacement 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

DEVICE DESCRIPTION

This submission consists of inclusion of additional variant to the existing devices Bencox Mirabo Cup System which is a cementless hip acetabular system (Metal on Poly Liner or Ceramic on Poly Liner) for hip arthroplasty. The subject device Bencox Mirabo Cup Multi Hole is similar to Bencox Mirabo Cup System cleared under K172806 and K162127 & K120924, with respect to material – Titanium alloy (ASTM F136), coating with pure Titanium powder (ASTM F1580), design, locking system, manufacturing, packaging and sterilization.

SUBSTANTIAL EQUIVALENCE

Bencox Mirabo Cup Multi Hole is similar to the 510(k) cleared devices as mentioned below with respect to indications, design, specifications, operating principles and material.

<table>
<tr><th>Device</th><th>Manufacturer</th><th>Trade Name</th><th>510(k)</th></tr>
<tr><td>Predicate</td><td rowspan="2">Corentec Co. Ltd.</td><td>Bencox Mirabo Cup [System]</td><td>K172806</td></tr>
<tr><td rowspan="3">Additional Predicates</td><td>Bencox Mirabo Cup [System]</td><td>K162127 &K120924</td></tr>
<tr><td rowspan="2">Biomet Inc.</td><td rowspan="2">G7 Acetabular Cup [System]</td><td>K140669</td></tr>
<tr><td>K121874</td></tr>
<tr><td>Reference</td><td>Stryker Orthopedics</td><td>Trident PSL</td><td>K983382; K143085</td></tr>
</table>

The subject devices Bencox Mirabo Cup Multi Hole and the predicate device Bencox Mirabo Cups are acetabular cups made of the same material and plasma-sprayed porous coatings with same pore size, porosity and coating thickness. The design, dimensional specification and locking mechanisms are identical to the previously cleared cups of the Bencox Mirabo Cup and hence subject devices Bencox Mirabo Cup Multi Hole will be compatible with same polyethylene acetabular liners, as well as all modular components and instrumentation cleared in the Bencox Mirabo Cup Acetabular System under K172806 and K162127 & K150007 & K120924.

The subject device Bencox Mirabo Cup Multi Hole is available in multi-hole design (8, 12 & 16 holes) in comparison to primary predicate, Bencox Mirabo Cup which is available in limited holes design (3 holes) cleared under K172806 and K162127 & K120924. The subject device Bencox Mirabo Cup Multi Hole, multi-hole design is similar to additional predicate, G7 Acetabular cup with limited & multi-hole designs with 3, 4, 11 & 16 holes.

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PERFORMANCE DATA

Performance testing requirements was analyzed by engineering risk analysis which showed that the inclusion of variant, subject devices – Bencox Mirabo Cup Multi Hole, to the cleared predicate devices Bencox Mirabo Cup System under K172806, did not change the worst case configuration tested for all the performance testing as the dimensional specification of both subject and predicate devices are exactly same, except for acetabular cup deformation testing as per ISO 7206-12. Other performance testing conducted for predicate devices Bencox Mirabo Cup System cleared under K172806 is still valid for inclusion of the subject devices, Bencox Mirabo Cup Multi Hole.
The results of the engineering risk analysis & deformation testing as per ISO 7206-12 showed that the subject devices, Bencox Mirabo Cup Multi Hole are expected to be safe and effective for the proposed indications and are substantially equivalent to the predicate device, and could perform similar to Bencox Mirabo Cup System under K172806.

STERILIZATION & PACKAGING

Both subject devices and predicate devices are subjected to gamma sterilization. The sterilization and packaging validation for a shelf life of 5 years as per ISO & ASTM standards confirming the stability and effectiveness of packaging of the sterilized product during the shelf-life, by evaluating changes by accelerated aging, as per ASTM F1980 Sterilization validation as per ISO 11137–1 & 2 Sterilization of health care products – Radiation ensures sterility of the components for a SAL of 10^{-6} valid for predicate devices, Bencox Mirabo Cup System, is also applicable to subject devices, Bencox Mirabo Cup Multi Hole, as there is no change in the worst case tested in predicate devices submission.

CONCLUSION

Overall Bencox Mirabo Cup Multi Hole included in this PMN is similar to the identified primary predicate device and additional predicates. The identified minor differences between the subject devices and predicates do not constitute a new intended use and the minor differences in the technological characteristics do not affect or raise new queries of safety and effectiveness based on successful analysis conforming to recognized performance standards for hip replacement devices and has been adequately addressed in this premarket notification.

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