



Food and Drug Administration
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Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Corentec Company, Limited
J.S. Daniel
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KOREA

April 29, 2016

Re: K152084

Trade/Device Name: BENCOX M Stem and Bencox ID Cemented Stem (with Centralizer)
& Bone Plug

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, JDI, KWY, LZO

Dated: March 28, 2016

Received: March 29, 2016

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. 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 Parts 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Mark N. Melkerson -S

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

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

Indications for Use

510(k) Number (if known)

K152084

Device Name

Bencox M Stem (Bencox Hip System) and Bencox ID Cemented Stem (with Centralizer) & Bencox Bone Plug

Indications for Use (Describe)

Bencox M Stem (Bencox 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

The Bencox ID Cemented Stem (with Centralizer) & Bencox Bone Plug is intended for cemented use in total or partial hip arthroplasty and 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

The Centralizer is intended to be used with Bencox ID Cemented Stem to centralize the femoral stem within the intramedullary canal.

The Bencox Bone Plug is intended to be used with cemented hip replacement procedures to control and restrict the flow of cement within the intramedullary canal.

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

Corentec Co., Ltd.

Bencox M Stem (Bencox Hip System) and
Bencox ID Cemented Stem (with Centralizer) & Bone Plug

25th April 2016

ADMINISTRATIVE INFORMATION

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DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name: Bencox M Stem (Bencox Hip System) & Bencox ID
Cemented Stem (with Centralizer) and Bencox Bone Plug

Common Name: Hip Prosthesis

Classification Regulations: 21 CFR 888.3358, 888.3390, 888.3350, 888.3353

Class: Class II

Product Codes: LPH, JDI, KWY, LZO

Classification Panel: Orthopedic Products Panel

Reviewing Branch: Orthopedic Devices Branch

INTENDED USE**Bencox M Stem (Bencox Hip System)**

Bencox M Stem (Bencox 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

BENCOX ID Cemented Stem (with Centralizer) & Bone Plug

The Bencox ID Cemented Stem (with Centralizer) & Bone Plug is intended for cemented use in total or partial hip arthroplasty and 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

The Centralizer is intended to be used with Bencox ID Cemented Stem to centralize the femoral stem within the intramedullary canal.

The Bencox Bone Plug is intended to be used with cemented hip replacement procedures to control and restrict the flow of cement within the intramedullary canal.

DEVICE DESCRIPTION**Bencox M Stem (Bencox Hip System) - Sterile**

The Bencox M Stem is a double tapered wedge shaped stem intended for press-fit partial or total hip arthroplasty. When used in total hip arthroplasty the stem is coupled to a Femoral Head and used with Bencox Acetabular Cups cleared under K103431, K112019,

K120924, K121665 & K150007. When used in partial hip arthroplasty Bencox M Stem is coupled to a Femoral Head and used with Bencox Bipolar Cup cleared under K112019.

Bencox M Stem is made of Ti6Al4V alloy conforming to ASTM F136. The proximal half of the stem is plasma sprayed coating of pure titanium as per ASTM F1580. The materials used in subject device, Bencox M Stem, have been cleared for use in K112019 & K150007 for Bencox ID Stem & Bencox ID Stem (offset). The stem has a tapered rectangular section. The stem has a neck with a standard 12/14 conical taper to couple to Bencox Femoral Heads which have been cleared earlier. The Bencox M Stem is available 13 sizes with CCD angle of 132°. The stem is available in 13 sizes.

All the above described technological characteristics of subject device is similar to the identified predicate devices.

BENCOX ID Cemented Stem (with Centralizer) & Bone Plug - Sterile

Bencox ID Cemented Stem has bone plug and centralizer as accessories. The Collarless Bencox ID Cemented Stem consists of a polished double tapered distal geometry which generates the radial compressive load in distal body. The neck shape is similar to cleared Corentec's hip femoral stems in K103431, K112019, K122099 and K150007. The standard Morse taper (12/14) is used for femoral head assembly similar to cleared devices to couple to Bencox Femoral Heads and their compatible acetabular components which have been cleared in previous premarket notifications. The Bencox ID Cemented Stem is available 06 sizes with CCD angle of 132°. Bencox ID Cemented Stem is made of SS alloy.

The deformable centralizer is made of PMMA with flexible wing like projections that extend outwards from the base of the centralizer and fits over the outside diameter of the stem tip. These projections contact the walls of the femoral canal, centralizing the hip stem within the canal. The hollow centralizer is designed to allow stem to engage distally within the cement mantle, subjecting the cement to compressive loading, and reducing end bearing of the stem directly onto the cement. The centralizer is a molded acrylic device manufactured from PMMA.

Bencox bone plug has a double flanged geometry very similar to the predicate devices. The plug blocks the propagation of the doughy bone cement downward in the medullary cavity. The proximal flange provides a proximal barrier, while the more flexible distal flange forms a secondary seal to prevent cement leakage. Bencox bone plug is manufactured from UHMWPE.

All the above described technological characteristics of subject device is similar to the identified predicate devices.

Accessory BENCOX Hip Instrumentation: (Non Sterile)

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 stainless steel and/or polymers and/or silicon which are cleared for use in previous premarket notifications of Corentec.

Bencox Hip System Instrumentation to be used Bencox M Stem (Bencox Hip System) & Bencox ID Cemented Stem is same with Instrumentation cleared under K103431, K112019, K120924 & K122099 along with the inclusion of instruments specific to Bencox M Stem such as Rasp, Impactor etc.

SUBSTANTIAL EQUIVALENCE

The subject devices are substantially equivalent in indications, design principles and technological characteristics to the following predicate devices, each of which has been determined by FDA to be substantially equivalent, as below,

Subject Devices	Predicate Device/s			
	Predicate Category	Manufacturer	Trade Name	510(k)
BENCOX M STEM	Primary	DePuy	TriLock	K010367
	Additional	Stryker	Allocade II	K103479 & K120578
BENCOX ID Cemented STEM (with Centralizer)	Primary	Stryker (Howmedica)	Exeter/Exeter V40 Stem	K803126; K011623; K110290
			Exeter Distal Centralizer	K974054
	Additional	DePuy	C Stem AMT Stem	K042959
			C Stem AMT Distal Centralizer	K042959 & K013350
BENCOX BONE PLUG	Primary	Smith & Nephew	Buck Cement Restrictor	K791125 (Referred in K023680)
	Additional	Zimmer	Allen Medullary Bone Plug	K001733

As described in the Device Description section, the technological characteristics, such as design, material, indications, and operating principles are similar to the identified predicate devices. The minor differences do not affect the safety and effectiveness of the device when used for the said indications, based on non clinical testing.

PERFORMANCE DATA

The Bencox M Stem (Bencox Hip System) and BENCOX ID Cemented Stem was subjected to a series of testing protocols to document the performance of the components and to demonstrate substantial equivalence. Non-clinical testing and analysis included FEA, mechanical fatigue testing, and static pull off testing, rotational torque testing, dynamic compression testing, corrosion and range of motion testing.

The testing methods are described in the standards, ISO 7206-4, ISO 7206-6, ISO 21535, ISO 7206-9, ISO 7206-10, ASTM F2009, and ASTM F1875. The results of this testing showed that the subject devices are expected to be safe and effective for the proposed indications and are substantially equivalent to the predicate devices.

STERILIZATION

For all sterile implants, following to gamma sterilization, the packaging was subjected to sterile barrier testing to validate a shelf life of 5 years as per ISO & ASTM standards which confirms 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 an SAL of 10^{-6} .

All non sterile instruments used in the surgery must be sterilized by the hospital, prior to use, as mentioned in the instrument IFU.

Both Bencox M Stem (Bencox Hip System) and BENCOX ID Cemented Stem (with Centralizer) & Bone Plug have same shelf life of 5 years, similar to other cleared sterile devices of Corentec Co., Ltd.

CONCLUSION

Overall, the Bencox M Stem (Bencox Hip System) and BENCOX ID Cemented Stem (with Centralizer) & Bone Plug has similarities to the predicate devices with the same intended use, same fundamental scientific technology, similar design features, same operating principles, same materials and are supplied Sterile. The safety and effectiveness of the subject devices are adequately supported by the substantial equivalence information, material information and analysis of data in this PMN. Any differences in technological characteristic between the subject and predicate devices do not raise new issues of safety or efficacy.