DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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December 1, 2016

Corentec Co., Ltd
J.S. Daniel
Senior Manager/Engineer -RA/QA
8F Chungho Tower, 483, Gangnam-daero
Seocho Gu, Seoul, 137-040 KR

Re: K160157
Trade/Device Name: LOPSA Modular Knee System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH
Dated: January 20, 2016
Received: January 22, 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 Part 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" (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 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,

Lori A. Wiggins -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K160157

Device Name

LOSPA Modular Knee System

Indications for Use *(Describe)*

The LOSPA Modular Knee System is intended for the treatment of diseases as follows:

• Painful, disabling joint disease of the knee resulting from non-inflammatory degenerative joint disease (including osteoarthritis, traumatic arthritis or avascular necrosis) or rheumatoid arthritis;
• Post-traumatic loss of knee joint configuration and function;
• Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability;
• Correction or revision of unsuccessful osteotomy, arthrodesis, or failure of previous arthroplasty procedure.

The LOSPA Knee System is intended for cemented application only.

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.

LOSPA Modular Knee System

24th Sept., 2016

ADMINISTRATIVE INFORMATION

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DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	LOSPA Modular Knee System
Common Name:	Total Knee Joint Replacement Prosthesis
Classification Regulations:	21 CFR 888.3560
Class:	II
Product Codes:	JWH, ~~MBH~~
Classification Panel:	Orthopedic Products Panel
Reviewing Branch:	Orthopedic Devices Branch

INDICATIONS FOR USE

The LOSPA Modular Knee System is intended for the treatment of diseases as follows:

- Painful, disabling joint disease of the knee resulting from non-inflammatory degenerative joint disease (including osteoarthritis, traumatic arthritis or avascular necrosis) or rheumatoid arthritis;
- Post-traumatic loss of knee joint configuration and function;
- Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability;
- Correction or revision of unsuccessful osteotomy, arthrodesis, or failure of previous arthroplasty procedure.

The LOSPA Knee System is intended for cemented application only.

DEVICE DESCRIPTION

The LOSPA Modular Knee System components are similar to "LOSPA Total Knee System" cleared under K110404, K121037 & K130673 which consists of Femoral Components, Tibial Base plate, Tibial Insert, Patellar Components and related Instrumentation and are Patella Femoral Tibial Knee Prosthesis Systems, intended for cemented total knee arthroplasty, and all have same indications for use. The subject components, is a line extension to include extension stems with stem plugs and offset adaptors, distal and posterior femoral augments.

A) LOSPA Modular Femoral Component

Femoral components are available in PS design only. There are 13 sizes, #1 to #16, except for #2, #10 & #15, each for left and right sides. The ranges of dimensions are the same for both subject devices, LOSPA Modular Knee System & cleared devices LOSPA TKR System under K110404 & K130673.

Similar to Corentec's cleared devices LOSPA TKR System all femoral components of LOSPA Modular Knee System are manufactured from cobalt-chromium-molybdenum alloy conforming to ASTM F75, Standard Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implants (UNS R30075).

B) LOSPA Modular Tibial Base plate (with Hole Cap)

LOSPA Modular Knee System tibial base plate with hole cap is based on the design of the LOSPA Knee System tibial base plate. Modular tibial base plate is available in 13 sizes, #1 to #16, except for #2, #10 & #15. The antero-posterior (AP) lengths range from 36 mm to 58 mm, and the medio-lateral (ML) length ranges from 55 mm to 86 mm.

Similar to Corentec's cleared devices LOSPA TKR System all tibial base bplates of LOSPA Modular Knee System are manufactured from cobalt-chromium-molybdenum

alloy conforming to ASTM F75, Standard Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implants (UNS R30075).

C) LOSPA Constrained Tibial Insert with locking rod

LOSPA Modular Knee System tibial insert constrained with locking rod is based on the design of the LOSPA Knee System tibial insert. This component doesn't have distinction of both sides (left side and right side).

Tibial insert constrained are available in PS type only. There are 13 sizes, #1 to #16, except for #2, #10 & #15. The bearing spacing (in the frontal plane, the distance between the femoral condyles), s either 36 mm or 44 mm. Similar to Corentec's cleared devices LOSPA TKR System all tibial inserts of LOSPA Modular Knee System are manufactured from ultra-high-molecular-weight polyethylene conforming to ASTM F648, Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants. The locking rod is made from CoCr alloy as per ASTM F1537, Standard Specification for Wrought Cobalt-28Chromium-6Molybdenum Alloys for Surgical Implants (UNS R31537, UNS R31538, and UNS R31539) and designed to constrain the tibial insert with the tibial base plate.

D) LOSPA Femoral Distal block with fixation bolt-Pocket type

Femoral distal block consist of fixation bolt at all time. They are available in 5mm, 10mm thickness. They are compatible with modular femoral component, but must be fixed through screw fixation. These parts are used to cover loss of bone in revision surgery.

Femoral distal block and femoral posterior block are manufactured from titanium alloy conforming to ASTM F136, Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Interstitial) Alloy for Surgical Implant Applications (UNSR56401)

E) LOSPA Femoral Posterior block with fixation bolt-Pocket Type

Femoral posterior block consist of fixation bolt at all time. They are available in 5mm, 10mm, 15 mm thickness. They are compatible with modular femoral component, but must be fixed through screw fixation. These parts are used to cover loss of bone in revision surgery.

Femoral distal block and femoral posterior block are manufactured from titanium alloy conforming to ASTM F136, Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI(Extra Interstitial) Alloy for Surgical Implant Applications (UNSR56401).

F) LOSPA Tibial Half Block with Fixation Bolt-Pocket Type

Tibial half block consists of fixation bolt at all time. They are available in 5mm, 10 mm, 15 mm thickness of medial or lateral sides. They are compatible with modular tibial base plate, but must be fixed through screw fixation. These parts are used to cover loss of bone in revision surgery.

Tibial half block is manufactured from titanium alloy conforming to ASTM F136, Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI(Extra Interstitial) Alloy for Surgical Implant Applications (UNSR56401)

G) LOSPA Offset Adaptor with Nut

Offset adaptor consist of screw locking nut at all time. Offset adaptor with nut don't have distinction of both sides (left side and right side). Offset adaptor has offset 2 to 8 mm length, and can be used with modular femoral component and modular tibial base plate, stem extension in revision surgery.

Offset adaptor nut are manufactured from cobalt-chromium-molybdenum alloy conforming to ASTM F1537, Standard Specification for Wrought Cobalt-28 Chromium-6 Molybdenum Alloys for Surgical Implants (UNS R31537, UNS R31538, and UNSR31539)

H) LOSPA Stem Extension-Cemented

LOSPA Stem extension-Cemented provides screw to raise fixed force with modular femoral component, modular tibial base plate without stem plug. And it can be used with offset adaptor optionally. LOSPA Stem extension-Cemented has Ø9~Ø20 mm. The Cemented stem extension lengths range from 10 mm to 180 mm *(5 mm increment till 20 mm and 10 mm increment till 180 mm).*

LOSPA Stem extension-Cemented are manufactured from cobalt-chromium-molybdenum alloy conforming to ASTM F1537, Standard Specification for Wrought Cobalt-28 Chromium-6 Molybdenum Alloys for Surgical Implants (UNS R31537, UNS R31538, and UNSR31539)

I) LOSPA Hole cap

LOSPA Hole cap is assembled with modular tibial base plate. If modular tibial base plate needs augment (tibial half block with fixation bolt), it will be removed from modular tibial base plate. And there is additional composition detached from LOSPA Modular tibial base plate with hole cap.

LOSPA Hole cap is manufactured from ultra-high-molecular-weight polyethylene conforming to ASTM F648, Standard Specification.

J) LOSPA Stem plug

LOSPA Stem plug is assembled with modular femoral component, modular tibial base plate unless it doesn't use stem extension for revision surgery.

LOSPA stem plug is manufactured from cobalt-chromium-molybdenum alloy conforming to ASTM F1537, Standard Specification for Wrought Cobalt-28 Chromium-6 Molybdenum Alloys for Surgical Implants (UNS R31537, UNS R31538, and UNSR31539)

SUBSTANTIAL EQUIVALENCE

LOSPA Modular Knee 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, as below,

Predicate Type	Manufacturer	Trade or Proprietary or Model Name	510(k)
Primary	**Zimmer**	**NexGen LCCK**	**K960279**
Additional	Stryker	Scorpio TS	K994128

Following devices are used as reference devices,

Manufacturer	Trade or Proprietary or Model Name	510(k)
Smith & Nephew	Genesis II Total Knee System	K962137
Plus Orthopedics	RT-Plus Modular Knee	K023667
Medacta International, SA	GMK Revision Knee System	K102437
Howmedica Osteonics Corp.	Scorpio NRG Knee System	K030978
DePuy	DePuy PFC Sigma Knee System	K060515
Corentec	Eaum (LOSPA) TKR System	K110404

PERFORMANCE TESTING- BENCH

The LOSPA Modular Knee System components were subjected to a series testing requirements to demonstrate substantial equivalence and included methods described in the following standards: ASTM F1800; ASTM F1223; ASTM F1814 and ISO 14243. Mechanical testing of the subject device consisted of tibial plate fatigue testing, constraint test, contact analysis, Insert disassembly test, and tibial insert post shear test, wear testing and augment & stem extension connectivity testing. LOSPA Modular TKR System performed either similar or better than comparable similar devices. Any differences in technological characteristic between the subject and predicate devices do not raise new issues of safety or efficacy.

At a high level, the LOSPA Modular Knee System has the following similarities to the predicate devices:

- has similar intended use,
- has similar indications for use,
- use similar operating principles,
- incorporates similar basic designs,
- incorporates similar materials, and
- is supplied sterile