December 11, 2019

Corentec Co., Ltd
Ms. Min Jeong Lee
Asst. Manager- Global RA
33-2, Banpo-daero 20-gil, Seocho Gu
Seoul, Republic of Korea - 06649

Re: K192507
Trade/Device Name: LOSPA II 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: September 10, 2019
Received: September 12, 2019

Dear Min Jeong Lee:

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,

Ting Song
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192507

Device Name

LOSPA II Knee System

Indications for Use *(Describe)*

LOSPA II 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.

LOSPA II 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 II Knee System

10th Sept., 2019

ADMINISTRATIVE INFORMATION

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DEVICE NAME AND CLASSIFICATION

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

INDICATIONS

The LOSPA II 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 II Knee System is intended for cemented application only.

DEVICE DESCRIPTION

The subject LOSPA II Knee System components are similar to predicate devices,

- LOSPA Total Knee System components cleared under K110404, K121037 & K130673 for subject devices - Femoral Components, Tibial Base plate, Tibial Insert, Patellar Components and related Instrumentation.
- LOSPA Modular Knee System cleared under K160157 for subject devices - Stemmed Tibial Base Plate and Stem Plug and related Instrumentation

The subject components are a line extension to LOSPA Knee System and consists of following components,

A) LOSPA II Femoral Component (PS-type and CR-type)

Femoral Components of LOSPA II Knee System are designed based on Femoral Components of LOSPA Knee System. Femoral component has two different types which match to Tibial Insert types: PS-type and CR-type. Each PS and CR-types have 12 sizes, from #01 to #12 for each right and left knee. The antero-posterior length ranges from 50 mm to 74 mm, and the medio-lateral length ranges from 59 mm to 77 mm. It is manufactured from cobalt-chromium-molybdenum alloy conforming to ASTM F75.

B) LOSPA II Tibial Insert (PS-type and CR-type)

Tibial Inserts of LOSPA II Knee System are designed based on Tibial Inserts of LOSPA Knee System, matching to Femoral Component types: PS-type and CR-type. Each PS and CR-types have 10 sizes, from #02 to #11. Tibial Insert is used at both right and left knee. The antero-posterior length ranges from 36 mm to 57 mm, and the medio-lateral length ranges from 57 mm to 86 mm. Tibial Inserts are recommended to match Femoral Components of two-size up and one-size down. The Tibial Inserts of LOSPA II have two material types: conventional UHMWPE and 7.5 Mrad cross-linked UHWMPE (XLPE) conforming to ASTM F648.

C) LOSPA II Tibial Baseplate (Standard and Stemmed)

Tibial Baseplate of LOSPA II Knee System has two different types: Standard and Stemmed. Standard base plate is designed based on our predicate device, LOSPA Knee System cleared under K110404/K121037. The Stemmed Tibial Baseplate is designed to add stem plug, or various types of stem extensions and based on our predicate device, LOSPA Modular Knee System cleared under K160157. Each Standard and Stemmed Baseplate has 10 sizes, from #02 to #11. The antero-posterior length ranges from 36 mm to 57 mm, and the medio-lateral length ranges from 57

mm to 86 mm. Each sizes exactly matches to same size of the Tibial Insert. It is manufactured from cobalt-chromium-molybdenum alloy conforming to ASTM F75.

D) LOSPA II Stem plug

LOSPA II Stem Plug is assembled with LOSPA II Stemmed Tibial Baseplate when the package is opened.. If Stem Extension is not used, the user can use it as it is assembled. Prior to use Stem Extension, the stem plug should be removed from the stem hole of the Tibial Baseplate. It is manufactured from cobalt-chromium-molybdenum alloy conforming to ASTM F1537.

LOSPA Stem Extensions cleared under K160157 and Patella Dome Type cleared under K110404 & K130673 is also compatible with LOSPA II Knee System.

SUBSTANTIAL EQUIVALENCE

LOSPA II 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 to pre-amendment devices:

Substantially equivalent products for LOSPA II Knee System are as follows,

Device	Manufacturer	Trade or Proprietary or Model Name	510(k)
Primary Predicate	Corentec Co. Ltd.	LOSPA Knee System	K110404
Additional Predicate's	Corentec Co. Ltd.		K121037; K130673
	Corentec Co. Ltd.	LOSPA Modular Knee System	K160157
	DePuy Orthopedics Inc.	Attune Knee System	K101433
Reference	Corentec Co. Ltd.	Coren (Bencox) Total Hip System	K103431

The subject and predicate devices all have femoral components designed specifically for the right and left knees, provided in a range of sizes, and all include cruciate retaining (CR) and posterior stabilized (PS) designs. Similarly, the subject device and the predicate device all include tibial base plate (tray) components for use on either the left or right tibia, and all tibial base plates incorporate a similar stabilizing keel design. UHMWPE tibial inserts in CR and PS designs are designed for use with the corresponding femoral components. The design features are similar to the predicate devices cleared in K110404, K121037, and K130673. A stemmed tibial baseplate and stem plug similar to the predicate cleared in K160157 is included and designed to accommodate stem plug or

stem extensions cleared under K160157. Crosslinked UHMWPE material included in this submission for tibial insert is compared favorably with predicate device, DePuy's Attune Knee System cleared under K101433.

The LOSPA II Knee System and the predicate device components are similar in overall shape and design & materials used. The subject device and the predicate devices encompass a similar range of physical dimensions, including the AP and ML dimensions of the femoral and tibial base plate components, the thickness of the tibial insert components.

PERFORMANCE TESTING- BENCH

The LOSPA II 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 F2083; ASTM F1814, ISO 14243 and ISO 21536. Mechanical testing of the subject device consisted of tibial plate fatigue testing, constraint test, contact analysis, Insert disassembly test, tibial insert post shear test, wear testing, and dislocation/jump distance and range of motion. For crosslinked UHMWPE testing was done as per ASTM F648 and ASTM F2565 requirements and the results were favorably compared to predicate device. Gamma Sterilization Validation as per ISO 11137 & Ethylene Oxide Sterilization Validation per ISO 11135 and residuals testing as per ISO 10993-7 & ISO 10993-10. Bacterial Endotoxin Testing (BET) conducted as specified in ANSI/AAMI ST72:2011.

LOSPA II Knee System performed either similar or better than comparable predicate devices and is 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, the LOSPA II Knee System has the following similarities to the predicate devices:

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