August 26, 2022

Corentec Co., Ltd.
Yoorim Bae
RA Manager
12, Yeongsanhong 1-gil, Ipjang-Myeon, Seobuk-Gu
Cheonan-si, Chungcheongnam-do 31056
Republic of Korea

Re: K222278
Trade/Device Name: LOSPA TKR System Instrumentation, EXULT TKR System Instrumentation
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, MBH, OOG
Dated: June 27, 2022
Received: July 29, 2022

Dear Yoorim Bae:

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 Ting Song, Ph.D., R.A.C.
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)*

K222278

Device Name
LOSPA TKR System Instrumentation

Indications for Use *(Describe)*

LOSPA TKR System is intended for use in total knee arthroplasty surgery for the following indications:

• 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 TKR 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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)*
K222278

Device Name
EXULT TKR System Instrumentation

Indications for Use *(Describe)*

EXULT 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.

EXULT 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807, this information serves as a Summary of Safety and Effectiveness for LOSPA, EXULT Knee Instruments changes.

Date: June 27, 2022

ADMINISTRATIVE INFORMATION

Manufacturer: Corentec Co., Ltd.
12, Yeongsanhong 1-gil, Ipjang-Myeon, Seobuk-Gu
Cheonan-si, Chungcheongnam-do, Rep. of Korea -31056
Telephone: +82-41-585-7114; Fax: +82-41-585-7113

Official Contact: Yoorim Bae
RA Manager
12, Yeongsanhong 1-gil, Ipjang-Myeon, Seobuk-Gu
Cheonan-si, Chungcheongnam-do, Rep. of Korea -31056
Ph: +82-41-410-7116 (Direct) ; Fax: +82-41-585-7113
Email: yoorim.bae@corentec.com

Trade or Proprietary Name:	LOSPA TKR System Instrumentation, EXULT TKR System Instrumentation
Common Name:	Orthopedic Surgical Instruments
Regulatory Class:	Class II
Regulation Number:	21CFR888.3560
Regulation Name:	Knee Joint Patellofemorotibial Polymer/Metal/Polymer Semi-Constrained Cemented Prosthesis
Product Code(s):	JWH, MBH, OOG
Panel code:	Orthopedics 87

Legally Marketed Device(s) to Which Equivalence is Claimed

510(k) Number		Trade Name	Submitter	Product Code
Primary	K160157	LOSPA Modular Knee System	Corentec Co.,Ltd	JWH, MBH
Reference	K192507	LOSPA II Knee System		JWH
	K110404	LOSPA Total Knee System (EAUM Total Knee System)		JWH
	K130673	LOSPA Total Knee Replacement System		JWH
	K200395	EXULT Knee Replacement System		JWH
	K201851	EXULT Knee Replacement System		JWH, OOG
	K212034	LOSPA TKR System		JWH, MBH

Reason for 510(k) Submission

The purpose of this submission is to include additional instruments for LOSPA Modular Knee System and EXULT Knee System.

DEVICE INFORMATION

A. Device Description

The subject devices in this special 510(k) are the surgical instruments for the LOSPA Modular Knee System and EXULT Knee System, and submitted as a line extension of optional instruments for Corentec's FDA-cleared reusable orthopedic knee joint replacement instruments. The subject instruments are part of Corentec' 510(k)-cleared knee product lines and are required to facilitate total knee arthroplasty procedures.

LOSPA Modular Knee System Instruments

Implant specific trials – the design of the connection part of the trials to the instrument has been revised due to customer's needs.

Guide, alignment instruments – the design of the cutting guides and alignments instruments have been revised due to customer's needs.

EXULT Knee System Instruments

AP sizer external rotation instrument and cutting block instruments have been developed to facilitate to check in posterior access during the operation based on US surgeon's request.

B. Intended Use

Corentec knee instruments are accessory devices and are intended to be used to assist in the implantation of LOSPA Knee Systems (Primary, Modular), EXULT Knee Replacement System in their cleared Indications for Use as provided below:

LOSPA Knee System, EXULT Knee Replacement System are 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, EXULT Knee Replacement System are intended for cemented application only.

C. Summary of Technological Characteristics

The subject instruments performed comparable to predicate devices and are as safe and effective as the predicate devices. Any differences in technological characteristic between the subject and predicate devices do not raise new issues of safety or efficacy. The subject instruments have the following similarities to the predicate devices:

- Have the same intended use,
- Have the same indications for use,
- Use the same operating principles,

- Incorporate the same basic designs,
- Incorporate the same/similar materials, and
- Are supplied non-sterile.

D. Non-Clinical Testing

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

- Dimensions measurement testing
- Assembly testing

E. Clinical and Animal Testing

No clinical or animal testing were required.

F. Substantial Equivalence Conclusion

Based on the similarities to the predicate devices and rationale to support substantial equivalence, the subject devices are substantially equivalent to the commercially available predicate devices.