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May 7, 2020

Corentec Co., Ltd
% Yoorim Bae
Asst. Manager-RA
Corentec Co., Ltd.
Banpo-daero 20-gil, 33-2, Seocho Gu,
Seoul, Seoul 06649
Republic of Korea

Re: K200395
Trade/Device Name: LOSPA II Knee System (EXULT Knee Replacement 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: April 7, 2020
Received: April 7, 2020

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,

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

K200395

Device Name

LOSPA II Knee System (EXULT Knee Replacement System)

Indications for Use *(Describe)*

LOSPA II Knee System (EXULT Knee Replacement System) is indicated 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 (EXULT Knee Replacement 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 (EXULT Knee Replacement System)

- Specification Inclusion

February 14, 2020

ADMINISTRATIVE INFORMATION

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DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	LOSPA II Knee System (EXULT Knee Replacement 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 FOR USE

The intended use of the added specification has not changed as a result of the modification of the predicate device cleared under LOSPA II Knee System, K192507.

The LOSPA II Knee System (EXULT Knee Replacement System) is indicated 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 (EXULT Knee Replacement System) is intended for cemented application only.

Legally Marketed Device to Which Substantial Equivalence is Claimed:
The LOSPA II Knee System (EXULT Knee Replacement System) (CR, PS) Femoral Component – K192507
The LOSPA II Knee System (EXULT Knee Replacement System) Instrumentation – K192507, K110404, K130673, K160157

DEVICE DESCRIPTION

The Additional components being added to the LOSPA II Knee Replacement System (EXULT Knee Replacement System) are:

- Revised Size 12 PS, CR Femoral Component
- Additional Size 13 PS, CR Femoral Component
- Instrumentation

The subject LOSPA II Knee System (EXULT Knee Replacement System) components specification inclusions are a line extension of Femoral Components and Instrumentation system. The following are the additional components,

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

Femoral Components of LOSPA II Knee System (EXULT Knee Replacement System) are designed based on Femoral Components of LOSPA II Knee System. Femoral component has two different types which match to Tibial Insert types: PS-type and CR-type. There is one additional size, #13 of each design (CR and PS), each for left and right sides, and one modified size #12 (CR and PS, each left and right). For both CR and PS designs, the ranges of dimensions are the same. All femoral components 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) Instrumentation

There are additional instruments for use with the system implant components.

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 Type	Manufacturer	Trade or Proprietary or Model Name	510(k)
Primary Predicate	Corentec Co. Ltd.	LOSPA II Knee System	K192507
Additional Predicates	Corentec Co. Ltd.	LOSPA Knee System	K130673 K110404 K121037 K160157 K190402
	Stryker Orthopaedics (Aka Howmedica Osteonics Corp.)	Triathlon Total Knee System	K173849 K172326
		Scorpio NRG Knee System	K042343 K071991

PERFORMANCE TESTING - BENCH

The LOSPA II Knee System (EXULT Knee Replacement System) additional components were justified by a series of testing requirements conducted on the worst-case predicate components of the system 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, which consisted of tibial plate fatigue testing, constraint testing, contact analysis, insert disassembly testing, tibial insert post shear testing, wear testing, dislocation/jump distance and range of motion. Mechanical testing of the additional components was not necessary as the minor size changes are consistent with the previously evaluated predicate device components.

CONCLUSIONS

The LOSPA II Knee System (EXULT Knee Replacement System) additional components are comparable to predicate devices and should be as safe and effective as predicate 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 II Knee System (EXULT Knee Replacement 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