September 12, 2024

Corentec Co., Ltd.
Seo Sanghee
Senior Manager
33-2, Banpo-daero 20-gil, Seocho Gu, Seoul, 06649
Republic of Korea

Re: K242401
Trade/Device Name: 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: August 12, 2024
Received: August 13, 2024

Dear Seo Sanghee:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Lixin Liu -S

Lixin Liu, Ph.D
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.

Submission Number *(if known)*

K242401

Device Name

EXULT Knee Replacement System

Indications for Use *(Describe)*

EXULT Knee Replacement 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 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.

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.

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510(k) Summary

ADMINISTRATIVE INFORMATION

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Date Prepared:	August 12, 2024

DEVICE NAME AND GENERAL INFORMATION

Trade/Proprietary Name:	EXULT Knee Replacement System
Common Name:	Total Knee Joint Replacement
Classification Regulations:	21 CFR 888.3560
Regulatory Class:	Class II
Product Codes:	JWH
Classification Panel:	Orthopedic Products Panel

Predicate device

Primary predicate device:
EXULT Knee Replacement System, Corentec Co., Ltd. (K192507, K242046).

Reference device:
LOSPA Total Knee System, Corentec Co., Ltd. (K110404, K121037, K130673)
Genesis II Total Knee System, Smith & Nephew, Inc. (K071071, K951987)

Device Description

The purpose of the submission is a line extension of the EXULT Tibial Insert (CPS-type) to the EXULT Knee Replacement System (K192507). The CPS-type Tibial Inserts are designed based on the design of the other previously cleared Tibial Inserts of the EXULT Knee Replacement System (PS-type,CR-type and UC-type). The CPS-type, which is constrained posterior stabilized, has a thicker and wider post which provides additional constraint as compared to the PS-type insert. The CPS-type Tibial Insert matches with Femoral Components of one-size up and down. The CPS-type Tibial Insert is symmetrical and used in both the right and left knee. It is only used in combination with the Femoral component/Tibial baseplate of the predicate device (K192507).

Indications for Use

EXULT Knee Replacement 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 Replacement System is intended for cemented application only.

Summary of Technological Characteristics

Device comparisons and performance testing indicate that the EXULT Tibial Insert (CPS-type) of the EXULT Knee Replacement System is substantially equivalent to the predicates in terms of intended use, indications, design, materials, performance characteristics and operational principles. It offers an additional option of constraint to the existing Tibial Inserts available with the EXULT Knee Replacement System.

Non-Clinical Testing

The Corentec Co., Ltd. has evaluated the subject EXULT Tibial Insert to determine substantial equivalence to the predicate devices. The following characterization parameters were considered.

- Wear Testing as per ISO 14242-1&2, ASTM F2003-02
- Fatigue test as per FDA guidance document Knee Joint Patellofemorotibial and Femorotibial Metal/Polymer Porous-Coated Uncemented Prostheses - Class II Special Controls Guidance Document for Industry and FDA, section 7.D - Posterior Stabilized Tibial Bearing Component
- Constraint test as per ASTM F1223
- Range of Motion as per ISO 21536
- Surface roughness as per ISO 7207-2
- Disassembly as per ASTM F1814

Substantial Equivalence Conclusion

Based on the above characterization parameters, the subject device is determined to be Substantially Equivalent (SE) to the predicate device with respect to safety and effectiveness.