April 17, 2025

Corentec Co., Ltd.
Sanghee Seo
Senior Manager
12, Yeongsanhong 1-gil, Ipjang-Myeon, Seobuk-Gu, Cheonan-si
Chungchongnam-do, 31056
Republic of Korea

Re: K250889
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: March 25, 2025
Received: March 25, 2025

Dear Sanghee Seo:

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K250889

Please provide the device trade name(s).

EXULT Knee Replacement System

Please provide your Indications for Use below.

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 EXULT Knee Replacement System is intended for cemented use only.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

Date: April 16, 2025

ADMINISTRATIVE INFORMATION

Manufacturer:	Corentec Co., Ltd. 12, Yeongsanhong 1-gil, Ipjang-Myeon, Seobuk-Gu, Cheonan-si, Chungchongnam-do, Republic of Korea (31056) Telephone: +82-41-585-7114 Fax: +82-41-585-7113
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DEVICE NAME AND GENERAL INFORMATION

Trade/Proprietary Name:	EXULT Knee Replacement System
Common Name:	Total Knee Joint Replacement
Classification Regulations:	21 CFR 888.3560
Regulation name:	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class:	Class II
Product Codes:	JWH
Classification Panel:	Orthopedic Products Panel

Predicate device

EXULT Knee Replacement System, Corentec Co., Ltd. (K242046)

Device Description

The purpose of this submission is to introduce EXULT Tibial Insert UCR (Ultra Congruent & Cruciate Retaining) which is a line extension to the EXULT Knee Replacement System.

The EXULT Tibial Insert UCR is a modification to the PCL (Posterior Cruciate Ligament) notch of the EXULT Tibial Insert UC (K242046). This change allows the EXULT Tibial Insert UC to be used

by surgeons who do not resect the PCL when implanting an EXULT Tibial Insert UC. Tibial Insert is used at both right and left knee. It is only used in combination with the same Femoral component and Tibial baseplate of the predicate device.

Indications for Use

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 EXULT Knee Replacement System is intended for cemented use only.

Summary of Technological Characteristics

There are no significant changes between the subject and predicate device, and the indications for use, principle of operation, specifications, size, materials, manufacturing process and fundamental scientific technology and the locking mechanism remain identical. The similarities between the subject device, the predicate and reference device are provided in the following table.

Type	Subject device	Predicate device
Device name	EXULT Knee Replacement System	EXULT Knee Replacement System
510(k) number	K250889	K242046
Material	UHMWPE (ASTM F648/ISO 5834-2)	UHMWPE (ASTM F648/ISO 5834-2)
Tibial insert & Tibial Base Plate	Fixed	Fixed
Locking Mechanism	Full peripheral capture snap fit locking with anterior hook and posterior foot	Full peripheral capture snap fit locking with anterior hook and posterior foot
Tibial AP/ML	36~57 / 57~86 mm	36~57 / 57~86 mm
Sterilization	EtO gas	EtO gas

The difference between the subject device and the predicate device is a design modification to the PCL notch. The subject device opens PCL notch compared to predicate device (K242046) .

Type	Subject device	Predicate device
Device name	EXULT Knee Replacement System	EXULT Knee Replacement System
510(k) number	K250889	K242046
PCL notch - Design	Open	Close
PCL notch – Position	Opening of the posterior region of the tibial spine where the PCL passes through.	Closing of the posterior region of the tibial spine where the PCL passes through.

Non-Clinical Testing

The following tests and evaluations were performed to demonstrate substantial equivalence includes:

- Contact area/pressure per ASTM F2083
- Interlocking test per ASTM F1814
- Wear of articular surface per ISO 14243-2/3
- Range of Motion analysis per ISO 21536
- Constraint analysis per ASTM F1223
- Endurance and deformation under high flexion per ASTM F2777

Clinical Testing

Clinical data was not needed to support the safety and effectiveness of the subject device.

Substantial Equivalence Conclusion

The substantial equivalence of the EXULT Knee Replacement System is based on similarities in indications of use, design features, material biocompatibility and composition, and performance to the predicate device listed above. Based on the similarities, EXULT Knee Replacement System is substantially equivalent to its predicate.