July 30, 2020

Corentec Co., Ltd
Sungwon Yang
Director, QA & RA
12, Yeongsanhong 1-gil, Ipjang-Myeon, Seobuk-Gu
Cheonan-si, Chungchongnam-do 31056
SOUTH KOREA

Re: K201851
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, OOG
Dated: June 29, 2020
Received: July 6, 2020

Dear Sungwon Yang:

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)*

K201851

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.

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510(K) SUMMARY

Corentec Co.,Ltd.

EXULT Knee Replacement System

- Specification Inclusion

June 29, 2020

ADMINISTRATIVE INFORMATION

Manufacturer: Corentec Co., Ltd.
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DEVICE NAME AND CLASSIFICATION

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

INTENDED 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.

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

DEVICE DESCRIPTION

The Additional components being added to the EXULT Knee Replacement System are:

- Instrumentation (Femoral Component Trial)

The subject EXULT Knee Replacement System components specification inclusions are a line extension of Instrumentation (Femoral Component trial). The following is the additional components.

A) Instrumentation (Femoral Component Trial)

A copy of a final femur prosthesis designed to be used during total knee arthroplasty to determine the correct alignment, size, and fit of the final prosthesis. It is one of a set of trial knee prostheses that match the different anatomical structures of the knee joint, and may be used in conjunction with a knee tibia trial prosthesis and a patella trial prosthesis. It is typically made of metal or polymer material. This instrument is a reusable device that must be sterilized prior to use.

Additional Femoral Component Trials are designed based on Femoral Component Trials of predicate device cleared EXULT Knee Replacement System Instrumentation under K200395. This femoral component trials are made of Stainless steel alloy conforming to ASTM F899 Standard Specification for Wrought Stainless Steels for Surgical Instruments.

SUBSTANTIAL EQUIVALENCE

EXULT Knee Replacement 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 EXULT Knee Replacement System are as follows,

Device	Manufacturer	Trade or Proprietary or Model Name	510(k)
Primary Predicate	Corentec Co. Ltd.	EXULT Knee Replacement System (Instrumentation)	K200395

Summary of Technological Characteristics:

EXULT Knee Replacement System additional instrumentation performed either similar 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 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 non-sterile

Non-Clinical Testing

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

- Dimensions measurement testing
- Assembly testing

The dimensions of additional instruments (Femoral component trials) are exactly same with predicate devices under K200395 and additional performance testing is unnecessary since the trial is not implanted.

Clinical Testing

Clinical testing was not required as a basis for substantial equivalence

STERILIZATION & PACKAGING

The EXULT Knee System Instrumentation is supplied non-sterile and cited predicate devices are non-sterile.

CONCLUSION

Corentec Co., Ltd. believes that the subject device is substantially equivalent to the legally marketed predicate device based on intended use, technology, material, as well as the mechanical testing and biocompatibility assessment.