September 23, 2024

Corin USA Limited
Marine De Paoli
Senior Regulatory Affairs Specialist
12750 Citrus Park Lane
Tampa, Florida 33625

Re: K241570
Trade/Device Name: Unity Total Knee System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee Joint Patellofemorotibial Polymer/Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Codes: JWH, OIY
Dated: August 23, 2024
Received: August 23, 2024

Dear Marine De Paoli:

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
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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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241570

Device Name
Unity Total Knee System

Indications for Use *(Describe)*
The Unity Total Knee System is intended for use in total knee arthroplasty in skeletally mature patients, to provide increased mobility and reduce pain by replacing the damaged knee joint articulation where there is evidence of sufficient sound bone to seat and support the components.

The General total knee arthroplasty indications include:
• Painful, disabling joint disease of the knee resulting from: degenerative arthritis, rheumatoid arthritis or post-traumatic 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
• Revision of previous unsuccessful knee replacement or other procedure, where soft tissue stability is adequate
• Fracture of the distal femur and/or proximal tibia that cannot be stabilized by standard fracture management techniques
• The posterior stabilized variant is also indicated for PCL instability requiring implant bearing surface geometries with increased anterior-posterior constraint and absent or non-functioning posterior cruciate ligament
The Unity Total Knee System is intended for cemented use, single use 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

510(k) #: K241570 Prepared on: 2024-09-19

Contact Details

Applicant Name: Corin USA Limited
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Device Name

Device Trade Name: Unity Total Knee System
Common Name: Knee prosthesis
Classification Name: Knee Joint Patellofemorotibial Polymer/Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulation Number: 21 CFR 888.3560
Product Code(s): JWH, OIY

Legally Marketed Predicate Devices

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K183533	Unity Total Knee System, Unity Knee CS Tibial Insert	JWH
K113060	Unity Total Knee System, Unity Knee CR Tibial Insert	JWH
K150090	Zimmer® Persona® Personalized Knee System, MC insert	JWH, OIY, MBH

Device Description Summary

The Unity Total Knee System is a fixed bearing total knee replacement system that consists of a cobalt chromium alloy (CoCr) femoral component, a UHMWPE (Ultra-High-Molecular-Weight-Polyethylene) or ECiMa (Vitamin E enriched advanced polyethylene) tibial insert, a CoCr tibial tray with a titanium alloy keel extension and all-polyethylene (UHMWPE) patellar component for use in primary and revision total knee arthroplasty. The Unity Total Knee System femoral component is provided in two variants, cruciate retaining (CR) and posterior stabilised (PS).

- The CR femoral component is intended for use in conjunction with the CR tibial insert or Medial Constrained (MC) tibial insert where the posterior cruciate ligament (PCL) is functional or in conjunction with a Condylar Stabilised (CS) tibial insert or MC tibial insert where the PCL is present but is lax or non-functioning or when the PCL is absent.
- The PS femoral component is intended for use in conjunction with the PS tibial insert where the posterior cruciate ligament is non-functioning or absent, resulting in joint instability, or in conjunction with the constrained posterior-stabilized (PS-C) tibial insert where there is instability of the lateral collateral ligament and/or medial collateral ligament (LCL/MCL).

The Unity Total Knee System patellar component is optional and for use with either the CR or PS femoral variants and is intended for use where replacement of the articular surface of the patella is required. The system also provides titanium alloy augment components including femoral augments, tibial augments, stem extensions and offset adapters.

The Unity Total Knee System is intended for use in total knee arthroplasty in skeletally mature patients, to provide increased mobility and reduce pain by replacing the damaged knee joint articulation where there is evidence of sufficient sound bone to seat and support the components.

The Unity Total Knee system was originally cleared in K113060. This submission is for the inclusion of an additional range of Unity Knee MC Tibial Inserts. The additional range of tibial inserts has the same intended purpose as those cleared in the original 510(k) submission (K113060).

Intended Use/Indications for Use

The Unity Total Knee System is intended for use in total knee arthroplasty in skeletally mature patients, to provide increased mobility and reduce pain by replacing the damaged knee joint articulation where there is evidence of sufficient sound bone to seat and support the components.

The General total knee arthroplasty indications include:

- Painful, disabling joint disease of the knee resulting from: degenerative arthritis, rheumatoid arthritis or post-traumatic 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
- Revision of previous unsuccessful knee replacement or other procedure, where soft tissue stability is adequate
- Fracture of the distal femur and/or proximal tibia that cannot be stabilized by standard fracture management techniques
- The posterior stabilized variant is also indicated for PCL instability requiring implant bearing surface geometries with increased anterior-posterior constraint and absent or non-functioning posterior cruciate ligament

The Unity Total Knee System is intended for cemented use, single use only.

Indications for Use Comparison

The subject Unity Total Knee System is identical to the predicate Unity Total Knee System (K183533, K113060) and Zimmer Persona Personalized Knee System (K150090) in terms of intended use. The subject Unity Total Knee System indications for use are identical to the indications for use of the predicate Unity Total Knee System.

The Unity Total Knee System indications for use are similar to the indications for use of the Zimmer Persona Personalized Knee System; they fall within the intended use of the predicate devices and the differences do not alter the intended therapeutic use of the subject device nor do they affect the safety and effectiveness of the device relative to the predicate.

Technological Comparison

The Unity Knee MC tibial insert features a high conformity on the medial condyle, similar to that of the existing Unity Knee Cruciate Sacrificing (CS) tibial insert (K183533), and a lower conformity on the lateral side, very similar to that of the existing Unity Knee Cruciate Retaining (CR) tibial insert (K113060).

Compared to the Unity Knee CS lateral condyle, the subject Unity Knee MC lateral condyle is less conforming. The Unity Knee CR medial condyle is less conforming compared to the subject Unity Knee MC medial condyle.

The Unity Knee MC tibial insert is identical to the Unity Knee CS insert and Unity Knee CR insert in terms of connected devices, footprint sizes, size range and thickness.

The Zimmer Persona Personalized Knee System Medial Congruent (MC) insert (K150090) has a similar asymmetrical tibial insert condyle shape that provides greater medial conformity and less lateral conformity.

Non-Clinical and/or Clinical Tests Summary

Non-clinical testing conducted to demonstrate substantial equivalence includes:

- Constraint determination in accordance with ASTM F1223-20
- Range of motion CAD assessment in accordance with ISO 21536:2023
- Contact pressure analysis in accordance with ISO 21536:2023
- Dynamic disassociation testing in accordance with ASTM F2723-21
- Usability testing

A wear assessment rationale for the Unity Knee MC tibial insert was also conducted.

The Unity Knee MC tibial insert is part of the Unity Total Knee System originally cleared in K113060. The micromotion assessment performed for the Unity Total Knee System is applicable to the Unity Knee MC tibial insert.

The Unity Knee MC Tibial Insert is made of the same material as the Apex Knee ECiMa tibial insert (K201611). The material characterization performed for the Apex Knee ECiMa tibial insert is applicable to the Unity Knee MC tibial insert.

Conclusions

The results of the specific mechanical testing performed on the Unity Knee MC Tibial Insert show that the device is substantially equivalent to the predicate devices. A comparison of intended use and indications for use also demonstrated substantial equivalence.