June 4, 2019

Corin USA Limited
Lucinda Gerber
Global Regulatory Affairs Manager
12750 Citrus Park Lane, Suite 120
Tampa, Florida 33625

Re: K183533
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 Code: JWH
Dated: May 2, 2019
Received: May 3, 2019

Dear Lucinda Gerber:

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,

Peter G. Allen -S

Digitally signed by Peter G. Allen -S
Date: 2019.06.04 13:50:39 -04'00'

For CAPT Raquel Peat, PhD, MPH, USPHS
Director
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

2. INDICATIONS FOR USE

510(k) Number (if known): K183533

Device Name: Unity Total Knee System

Indications for Use:

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 Knee™ is intended for cemented use, single use only.

Prescription Use __X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

3. 510(K) SUMMARY

1. **Applicant/Sponsor:** Corin USA Limited
   Distributor 12750 Citrus Park Lane
   Suite 120, Tampa, FL 33625
   Establishment Registration No.: 1056629

2. **Contact Person:** Lucinda Gerber, BA (Hons)
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3. **Date:** December 18, 2018

4. **Proprietary Name:** Unity Total Knee System

5. **Common Name:** Knee Prosthesis

6. **Product Code(s):** JWH

7. **Classification Name:** Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prostheses (21CFR 888.3560)

8. **Legally Marketed Devices to which Substantial Equivalence is claimed:**
   - Corin Unity Total Knee System (K113060)
   - Stryker Triathlon® CS (Condylar Stabilizing) Lipped Insert (K063423)

9. **Device Description:**

The Unity Knee™ is a fixed bearing total knee replacement system that consists of a Cobalt Chromium Alloy (CoCr) femoral component, a UHMWPE polyethylene tibial insert, a Cobalt Chromium Alloy (CoCr) tibial tray with a Titanium Alloy keel extension and all-polyethylene patellar component for use in primary and revision total knee arthroplasty. The Unity Knee™ femoral component is provided in two variants, cruciate retaining (CR) and posterior stabilized (PS).

- The Unity Knee™ CR femoral component is intended for use in conjunction with the CR tibial insert where the posterior cruciate ligament (PCL) is functional or in conjunction with a Unity Knee™ CS tibial insert only where the PCL is present but is lax or non-functioning or when the PCL is absent.
- The Unity Knee™ PS femoral component and tibial insert variant is indicated for use where the posterior cruciate ligament is non-functioning or absent, resulting in joint instability.

The Unity Knee™ patellar component is optional for use with either the CR or PS variant and is indicated 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 and stem extensions.

The Unity Knee™ 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™ CS Tibial Inserts. The additional range of Tibial Insert has the same intended purpose as those cleared in the original 510(k) submission (K113060).

10. Intended Use / Indications:

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 Knee™ is intended for cemented use, single use only.

11. Summary of Technologies / Substantial Equivalence:

The Unity Knee™ CS tibial insert, subject to this submission is similar to the Stryker Triathlon® CS (Condylar Stabilizing) Lipped Insert (K063423) in terms of design, material, type of bearing, intended use and indication of use. The predicate is supplied in different variants, where the tibial insert can be made from either ultra-high molecular weight polyethylene (UHMWPE) or highly cross linked polyethylene (HXLPE). The focus of the variant selected is the fixed tibial insert made from “UHMWPE”, where the Unity Knee™ CS Tibial Insert is similar to the predicate devices above.

The Unity Total Knee System (CR Tibial Insert) (K113060) is also added as a predicate device because the tibial insert material, indication of use and fixture design between the tibial insert to the tibial tray are identical. The sizes are also similar, where both tibial inserts comes in nine (9) sizes. The difference in the sizing is the range of thickness provided with Unity Knee™ CS Tibial Insert.

Based on these similarities, the Unity Knee™ CS Tibial insert is believed to be substantially equivalent to the predicate devices.

12. Non-Clinical Testing:

Non-clinical testing and analysis for the Unity Knee™ CS tibial insert includes dynamic disassociation test in line with ASTM F2723-13a, constraint test in line with ASTM F1223-14, Range of motion in line with ASTM 2083-12 and contact pressure test.

The tibial insert & fixed tibial tray assembling / disassembling test, micromotion assessment & wear testing were not undertaken as the design of latching mechanism between the tibial tray and tibial insert is identical to that of the to that of the Unity Total Knee System (CR/PS tibial insert). Therefore, equivalency claim for the Unity Knee™ CS tibial insert.

The results of this testing show that the Corin Unity Knee™ CS Tibial is substantially equivalent to the predicate device.

Bacterial Endotoxin Testing (BET) has been conducted on finished, sterilized product, using Limulus Amebocyte Lystate (LAL) kinetic chromogenic methodology.

13. Clinical Testing:

Clinical testing was not necessary to determine substantial equivalence between the additional components of the Unity Knee™ CS tibial insert and the predicate devices.