



Corin USA Limited
Lorraine Mander
Regulatory Affairs Associate
12750 Citrus Park Lane
Tampa, Florida 33625

January 17, 2018

Re: K173884

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: December 20, 2017

Received: December 21, 2017

Dear Lorraine Mander:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Katherine D. Kavlock -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)

K173884

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.

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 indicated 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.

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3. 510(K) SUMMARY

- 1. Applicant/Sponsor:** Corin USA
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Establishment Registration No.: 1056629
- 2. Contact Person:** Lorraine Mander
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- 3. Date:** December 20, 2017
- 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 prosthesis (21CFR888.3560)
- 8. Legally Marketed Devices to which Substantial Equivalence is claimed:**
- Unity™ Total Knee System (K113060)

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 total knee arthroplasty. The Unity Knee™ is provided in two variants, cruciate retaining (CR) and posterior stabilized (PS). The Unity Knee™ CR is intended for use in instances where the posterior cruciate ligament (PCL) is functional. The Unity Knee™ PS variant is utilized when a total knee replacement is indicated, and the posterior cruciate ligament is non-functioning or absent, resulting in joint instability. The

Unity Knee™ patellar component is optional and is used in situations 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 femoral and tibial augments. The additional range of augments have the same intended purpose as those cleared in the original 510(k) submission (K113060).

10. Intended Use / Indications:

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.

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
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- 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 indicated for cemented use, single use only.

11. Summary of Technologies / Substantial Equivalence:

The Unity™ Total Knee System augments, subject of this submission, are identical in terms of intended use and indications, fixation, compatible components and are manufactured from the same materials as the predicate Unity™ Total Knee augments (K113060).

Additionally, the Unity augments, the subject device, are similar to the predicate (K113606) in terms of design and size range. Based on the similarities, Corin believes that the Unity™ Total Knee System augments are substantially equivalent to the predicate devices.

12. Non-Clinical Testing:

Non-clinical testing and analysis included torsional assembly, shear disassembly, torsional disassembly, cyclic disassembly and cyclic fretting in line with ASTM F1814-15. Cyclic testing has been conducted based on ASTM F1800-12. The results of this testing show that the Unity™ Total Knee System augment is expected to be safe and effective for the proposed indications and 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 Unity™ Total Knee System augment and the predicate devices.