DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 13, 2017

Corin USA Limited
Rachel King
Regulatory Affairs Associate
5670 W Cypress Street, Suite C
Tampa, Florida 33607

Re: K170808
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 30, 2017
Received: May 31, 2017

Dear Rachel King:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mark N. Melkerson -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170808

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, 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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

1. 510(K) SUMMARY

1. Applicant/Sponsor: Corin USA
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3. Date: March 16, 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:

- Corin Unity Total Knee System (K113060)

9. Device Description:

The Corin Unity Knee System is a fixed bearing total knee replacement system that consists of a femoral component, tibial insert, tibial tray and all-polyethylene patellar component for use in primary total knee arthroplasty. The Unity Knee System is provided in two variants, cruciate retaining (CR) and posterior stabilized (PS). The Unity CR Total Knee System is intended to accommodate the posterior cruciate ligament (PCL) if it is present. The Unity posterior stabilized variant is utilized when total knee replacement is indicated, and the posterior cruciate ligament is non-functioning or absent, resulting in joint instability. The Unity system patellar component is optional and is used in situations where replacement of the articular surface of the patella is required. The system also provides augment components including femoral wedges, tibial wedges, a short keel extension and stem extensions.

The Unity Total Knee system was originally cleared in K113060. This submission is for the addition of one size of stem extension size to the range, a size 30mm in two available diameters 10mm and 14mm. Like the originally cleared stem extensions the 30mm has the same identical modular taper connection.

10. Intended Use / Indications:

Intended 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.

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
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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, single use only.

11. Summary of Technologies / Substantial Equivalence:

The Unity Total Knee System components, subject of this submission, are identical in terms of intended use and indications and are manufactured from the same materials as the predicate Unity Total Knee stem extensions (K113060). These components are similar to the predicates Unity Total Knee stem extensions (K113606) in terms of design. Based on these similarities, Corin believes that the Unity Total Knee System is substantially equivalent to the predicate devices.

12. Pyrogenicity Assessment:

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

13. Non-Clinical Testing:

Non-clinical testing and analysis included fatigue endurance and assessment of fretting properties. The results of this testing show that the Corin Unity Total Knee System stem extension is expected to be safe and effective for the proposed indications and is substantially equivalent to the predicate device.

14. Clinical Testing:

Clinical testing was not necessary to determine substantial equivalence between the Unity Total Knee System stem extension and the predicate devices.