Corin USA Limited
Lucinda Gerber
Global Regulatory Affairs Manager
5670 W Cypress Street, Suite C
Tampa, Florida 33607

October 31, 2017

Re: K170359
Trade/Device Name: Trinity Dual Mobility System
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip Joint Metal/Ceramic/Polymer Semi-Constrained Cemented Or Nonporous Uncemented Prosthesis
Regulatory Class: Class II
Product Code: LZO, MEH
Dated: September 28, 2017
Received: September 29, 2017

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. 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 (DICE) 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 (DICE) 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)*
K170359

Device Name
Trinity™ Dual Mobility System

Indications for Use *(Describe)*
The Trinity™ Dual Mobility System is intended for use in the following indications:

1. Non-inflammatory degenerative joint disease, including osteoarthritis & avascular necrosis
2. Rheumatoid Arthritis
3. Correction of functional deformity
4. Revision of previously failed total hip arthroplasty,
5. Patients at increased risk of dislocation
6. Developmental dysplasia of the hip (DDH)

The TrinityTM Dual Mobility System is indicated for cementless 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

3. 510(k) SUMMARY

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

2. **Contact Person:** Lucinda Gerber, BA (Hons)
Global Regulatory Affairs Manager
Corin Ltd / Corin USA
1 (772) 321-2478
lucinda.gerber@coringroup.com

3. **Date:** February 2, 2017

4. **Proprietary Name:** Trinity™ Dual Mobility System

5. **Common Name:** Hip Prosthesis

6. **Product Code(s):** LZO, MEH

7. **Classification Name:** 888.3353 - Hip joint metal/ceramic/ polymer semi-constrained cemented or Nonporous uncemented prosthesis

8. **Legally Marketed Devices to which Substantial Equivalence is claimed:**
   - Stryker MDM™ (K103233)
   - Zimmer Biomet G7 Dual Mobility System (K150522)
   - Corin Trinity Acetabular System (K110087, K111481, K131647)

9. **Device Description:**

The Trinity™ Dual Mobility System is a modular acetabular system consisting of two articulating surfaces in the same joint space. The system includes a highly polished Cobalt Chromium Alloy (CoCr) liner that articulates with an ECiMa™ (Vitamin E Ultra-High-Molecular-Weight Polyethylene) mobile insert. A Trinity™ femoral head, 22mm or 28mm CoCr or 28mm BIOLOX® *delta* heads, articulates within the ECiMa™ mobile insert to allow for a second articulation. The Trinity™ Dual Mobility System is intended to be used only with compatible Trinity™ acetabular Shells. The Trinity™ Dual Mobility System is designed for use with any Corin femoral stem with a 12/14 taper connection. The Trinity™ Dual Mobility System is intended for use in primary and revision total hip arthroplasty (THA) to provide increased stability and reduce pain by replacing the hip joint articulation where there is evidence of sufficient sound bone to seat and support the components.

The Trinity™ Dual Mobility System is intended to be used with the following approved devices:

- Trinity™ Acetabular Shells (Sizes 2- 5) (K093472, K123705, K122305, K130128)
- 28mm CoCr heads (K110087, K131647)
- 28mm BIOLOX® *delta* Ceramic Heads (K103120)

10. Intended Use / Indications:

The Trinity™ Dual Mobility system is intended for use in the following indications:

1. Non-inflammatory degenerative joint disease, including osteoarthritis & avascular necrosis,
2. Rheumatoid Arthritis,
3. Correction of functional deformity,
4. Revision of previously failed total hip arthroplasty,
5. Patients at increased risk of dislocation,
6. Developmental dysplasia of the hip (DDH),

The TrinityTM Dual Mobility System is indicated for cementless use only.

11. Summary of Technologies/Substantial Equivalence:

The Trinity™ Dual Mobility System is similar to the predicate devices (K110087, K111481, K131647, K150522 and K103233) in terms of intended use and indications, materials, sizes, design and testing. Based on these similarities, the Trinity™ Dual Mobility System is believed to be substantially equivalent to the predicate devices.

12. Pyrogenicity Assessment:

Bacterial endotoxin testing was conducted and was found to meet the expected endotoxin limits.

13. Non-Clinical Testing:

Non-clinical testing conducted to demonstrate substantial equivalence includes static tests (Push-out, lever-out, torque-off) and Dynamic Tests (Impingement, corrosion, range of motion, and wear). The results of this testing show that the Trinity™ Dual Mobility System 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 Trinity™ Dual Mobility System and the predicate devices.