April 11, 2018

Corin USA Limited
Rachel King
Regulatory Affairs Associate
12750 Citrus Park Lane
Tampa, Florida 33625

Re: K173880
Trade/Device Name: Corin TriFit^{TM} CF Hip Stem
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: MEH, LZO, KWL, KWY, LPH, MBL
Dated: March 5, 2018
Received: March 6, 2018

Dear Ms. 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.

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173880

Device Name
Corin TriFit™ CF Hip Stem

Indications for Use *(Describe)*
The indications for the Corin TriFit™ CF Hip Stem as a total hip arthroplasty and as a hip hemiarthroplasty include:

- Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
- Rheumatoid arthritis
- Correction of functional deformity
- Treatment of non-union and femoral neck fractures of the proximal femur
- Developmental Dysplasia of the Hip (DDH)
- Previously failed hip surgery

The Corin TriFit™ CF Hip Stem 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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:** Rachel King, BSc (Hons)
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3. **Date:** December 20, 2017

4. **Proprietary Name:** Corin TriFit™ CF Hip Stem

5. **Common Name:** Hip Prosthesis

6. **Product Code(s):** MEH, LZO, KWL, KWY, LPH, MBL

7. **Classification Name:** Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (21CFR 888.3353)

   Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis (21CFR 888.3390)

   Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis (21CFR 888.3360)

8. **Legally Marketed Devices to which Substantial Equivalence is claimed:**
   - Ortho Development Corporation Alpine Hip Stem (K141001) (Primary predicate)
   - Corin TriFit™ TS Hip (K121563 and K153772)

9. **Device Description:**

The Corin TriFit™ CF Hip Stem is a tapered stem design manufactured from titanium alloy (Ti6Al4V) (ASTM F136) with a layer of commercially pure titanium (ISO 5832-2:1999, ASTM F1580-01) and calcium phosphate coating (ASTM F1609-08) applied. The Corin TriFit™ CF Hip Stem is available in a range of sizes in a 127° standard offset and a 127° lateralized high offset. The device is intended to be used with Corin 12/14 modular taper heads.

The TriFit™ CF Hip Stem is intended to provide increased patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components.

10. Intended Use / Indications:

The indications for the Corin TriFit™ CF Hip Stem as a total hip arthroplasty and as a hip hemiarthroplasty include:

- Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
- Rheumatoid arthritis
- Correction of functional deformity
- Treatment of non-union and femoral neck fractures of the proximal femur
- Developmental Dysplasia of the Hip (DDH)
- Previously failed hip surgery

The Corin TriFit™ CF Hip Stem is indicated for cementless use only.

11. Summary of Technologies / Substantial Equivalence:

The Corin TriFit™ CF Hip Stem is similar to the Ortho Development Corporation Alpine Hip Stem (K141001) stem in terms of materials, size, designs, performance, intended use and indications for use. The coating, a titanium plasma spray with a layer of calcium phosphate is identical to the coating for the TriFit™ TS Hip Stem (K121563, K153772) in terms of materials and performance. The design of the neck on the TriFit™ CF Hip Stem is identical to that of the TriFit™ TS Hip Stem (K121563, K153772). Based on these similarities, the TriFit™ CF Hip Stem is believed to be substantially equivalent to the predicate devices.

12. Non-Clinical Testing:

Non-clinical testing and analysis included mechanical fatigue testing of the neck and stem and range of motion testing. The results of this testing show that the Corin TriFit™ CF Hip Stem 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 additional components of the Corin TriFit™ CF Hip Stem and the predicate devices.