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

June 20, 2017

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

Re: K162942
Trade/Device Name: Corin MetaFix 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: LZO, KWL, KWY, JDI, MEH, OQI
Dated: May 30, 2017
Received: May 31, 2017

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.

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)*

K162942

Device Name
Corin Metafix Hip Stem

Indications for Use *(Describe)*

The indications for the Corin MetaFix Hip as a total hip arthroplasty, and when used in combination with a Corin hemi arthroplasty head, as a hip hemi-arthroplasty, 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
- Developmental dysplasia of the hip (DDH) or congenital dysplasia of the hip (CDH)

The MetaFix Hip is intended 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
   Distributor
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   Tampa, Florida 33607
   Establishment Registration No.: 1056629

2. **Contact Person:**
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3. **Date:** October 19, 2016

4. **Proprietary Name:** Corin MetaFix Hip Stem

5. **Common Name:** Hip Prosthesis

6. **Product Code(s):** LZO, KWL, KWY, JDI, MEH, OQI

7. **Classification Name:**
   21 CFR 888.3353 – Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
   21 CFR 888.3390 – Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis
   21 CFR 888.3360 – Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis
   21 CFR 888.3350 – Hip joint metal/polymer semi-constrained cemented prosthesis

8. **Legally Marketed Devices to which Substantial Equivalence is claimed:**
   - Corin Metafix Hip Stem (K082525, K120362, K121439, K130634, K131952 and K153381)

9. **Device Description:**

The Metafix Hip is a tapered stem manufactured from titanium (Ti6Al4V) with a layer of hydroxyapatite (HA) Coating applied. The Metafix™ Hip is available in a 135° standard offset (collared and collarless), 135° lateralized high offset (collarless), a 125° standard offset (collared and collarless), a 125° short neck (collared) and a 135° short neck (collared). The device is intended to be used with 12/14 modular taper heads.

The Metafix hip 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.

The Corin MetaFix Hip Stem was originally cleared in K082525, K120362, K121439, K130634, K131952 and K153381. The purpose of this submission is to modify the labeling to remove an indication from the indications for use for the MetaFix Hip Stem, for clarity to ensure safe or effective use. The design and compatible components for use with the Corin MetaFix Hip stem subject of this submission are identical to that of the predicate device K082525, K120362, K121439, K130634, K131952 and K153381.

10. Intended Use / Indications:

The indications for the Corin MetaFix Hip as a total hip arthroplasty, and when used in combination with a Corin hemi arthroplasty head, as a hip hemi-arthroplasty, 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
- Developmental dysplasia of the hip (DDH) or congenital dysplasia of the hip (CDH)

The Corin MetaFix Hip is intended for cementless use only.

11. Summary of Technologies / Substantial Equivalence:

The MetaFix Hip Stem subject of this submission is identical to the predicate MetaFix Hip Stem (K082525, K120362, K121439, K130634, K131952 and K153381) in design, materials, coating, sizes and similar in terms of intended use/indications for use. Based on these similarities, Corin believes that the MetaFix Hip Stem is substantially equivalent to the predicate device.

12. Non-Clinical Testing:

A comparison of indications for use and contraindications demonstrate substantial equivalence. Bacterial Endotoxin Testing (BET) has been conducted on finished, sterilised product, using Limulus Amebocyte Lystate (LAL) kinetic chromogenic methodology.

13. Clinical Testing:

Clinical testing was not necessary in this Traditional 510(k).