April 7, 2022

Corin USA Limited
Janet Grannells
Senior Regulatory Affairs Specialist
5670 W. Cypress St., Suite C
Tampa, Florida 33607

Re: K212069
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, JDI, KWL, KWY, MEH, OQI
Dated: March 3, 2022
Received: March 4, 2022

Dear Janet Grannells:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Limin Sun, Ph.D.
Acting Assistant Director
DHT6A: Division of Joint
Arthroplasty Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212069

Device Name
Corin MetaFix™ Hip Stem

Indications for Use *(Describe)*
The indications for the Corin MetaFix™ Hip Stem 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) and congenital dysplasia of the hip (CDH)

The Corin MetaFix™ 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.

3. 510(K) SUMMARY

1. Applicant/Sponsor:
Distributor

Corin USA Limited
12750 Citrus Park Lane
Suite 120, Tampa, FL 33625
Establishment Registration No.: 1056629

2. Contact Persons:

Janet Grannells, BSc (Hons), Assoc CIPD
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3. Date: 19 April 2021

4. Proprietary Name: Corin MetaFix™ Hip Stem

5. Common Name: Hip Prosthesis

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

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)

Hip joint metal/polymer semi-constrained cemented prosthesis. (21CFR 888.3350)

8. Legally Marketed Devices to which Substantial Equivalence is claimed:

- Corin MetaFix Hip Stem (K082525 (primary predicate), K120362, K121439, K153381 & K162942)

9. Device Description:

The MetaFix™ Hip is a tapered stem manufactured from titanium alloy (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 (collared and 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.

10. Intended Use / Indications:

The indications for the Corin MetaFix™ Hip Stem 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 Stem is indicated for cementless use only.

11. Summary of Technologies / Substantial Equivalence:

Lateralized collared stems and additional sizes of the short neck collared stem are being added to the existing MetaFix stem range

The Corin MetaFix™ Lateralized Collared Hip Stem has the same intended use and indications and is manufactured from the same materials as the predicates (K082525, K120362, K121439, K153381 & K162942). The Corin MetaFix™ Lateralized Collared Hip Stem has a tapered metaphyseal flare with proximal horizontal grooves, distal vertical grooves and medial calcar grooves similar to the predicate Corin MetaFix™ Standard Collared Hip Stems.

The Corin MetaFix™ Short Neck Collared Hip Stem (Size 3-8 for both 135° & 125°) are similar in design to short neck design of the Corin MetaFix™ Collared Hip Stem Short Neck Variant in K153381 and similar in sizes to the MetaFix™ Standard Collared Hip Stems.

Based on these similarities, Corin believes that the MetaFix™ Lateralized Collared Hip Stem and the additional short neck collared stem is substantially equivalent to the predicate device.

12. Non-Clinical Testing:

Non-clinical testing and analysis included mechanical fatigue testing of the neck and stem. A range of motion assessment was conducted. The results of this testing show that the Corin MetaFix™ Lateralised Collared Hip Stem and larger MetaFix™ Collared Short Neck Hip Stems are expected to be safe and effective for the proposed indications and is substantially equivalent to the predicate device.

Applicable Standards associated with non-clinical testing:

- BS ISO 7206-4:2010+A1:2016 Implants for surgery. Partial and total hip joint prostheses. Determination of endurance properties and performance of stemmed femoral components
- BS ISO 7206-6:2013 Implants for surgery. Partial and total hip joint prostheses. Endurance properties testing and performance requirements of neck region of stemmed femoral components
- BS EN ISO 21535:2009+A1:2016 Non-active surgical implants. Joint replacement implants. Specific requirements for hip-joint replacement implants

13. Clinical Testing:

Clinical testing was not necessary to determine substantial equivalence between the Corin MetaFix™ Lateralized Collared Hip Stem, Corin MetaFix™ Collared Short Neck Hip Stem and the predicate devices.