DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 21, 2016

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

Re: K153381
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, OQI, MEH, KWL, KWY, JDI
Dated: November 20, 2015
Received: November 23, 2015

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 Parts 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" (21CFR 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 yours,

Lori A. Wiggins -S

for
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)*
K153381

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 Corin hemi-arthroplasty femoral heads, as a hemi-arthroplasty, include:

- Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
- Rheumatoid arthritis
- Correction of functional deformity
- Treatment of non-union, femoral neck and trochanteric fractures of the proximal femur
- Developmental dysplasia of the hip (DDH) or congenital dysplasia of the hip (CDH)

The Corin Metafix Hip Stem is intended for cementless, 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.

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3. 510(K) SUMMARY

1. Applicant/Sponsor:

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Registration No.: 1056629

2. Contact Person:

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3. Date: November 19, 2015

4. Proprietary Name: Corin Metafix Hip Stem

5. Common Name: Hip Prosthesis

6. Product Codes: LZO, KWL, KWY, JDI, OQI, MEH

7. Classification Name:

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/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (21CFR 888.3353)

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, K121439 & K120362)
- Depuy Orthopaedics Corail AMT Hip System (K042992)
- Corin TriFit TS Hip Stem (K121563)

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.

10. Intended Use / Indications:

The indications for the Corin Metafix Hip Stem as a total hip arthroplasty and, when used in combination with Corin hemi-arthroplasty femoral heads, as a hemi-arthroplasty, include:

- Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
- Rheumatoid arthritis
- Correction of functional deformity
- Treatment of non-union, femoral neck and trochanteric fractures of the proximal femur
- 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:

The Corin Metafix Collared Hip Stem has the same intended use and indications and is manufactured from the same materials as the predicates (K082525, K120362 & K121439). The Corin Metafix 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 Hip Stems.

The Corin Metafix Collared Hip Stem is similar to the DePuy Corail AMT Hip System (K042992) in that it has proximal horizontal grooves, a proximal collar, distal vertical grooves and medial calcar grooves.

The Corin Metafix Collared Hip Stem short neck variants are similar in design and measurements to the neck design of the Corin TriFit TS Hip Stem. Based on these similarities, Corin believes that the Metafix Collared Hip 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 and range of motion analysis. The results of this testing show that the Corin Metafix Collared Hip Stem is expected to be safe and effective for the proposed indications and is substantially equivalent to the predicate device.

13. Clinical Testing:

Clinical testing was not necessary to determine substantial equivalence between the Corin Metafix Collared Hip Stem and the predicate devices.