Corin USA Limited
Homer Trieu
Regulatory Affairs Specialist
12750 Citrus Park Lane
Tampa, Florida 33625

June 5, 2019

Re: K183114
Trade/Device Name: Corin BiPolar-i
Regulation Number: 21 CFR 888.3390
Regulation Name: Hip Joint Femoral (Hemi-Hip) Metal/Polymer Cemented Or Uncemented Prosthesis
Regulatory Class: Class II
Product Code: KWY
Dated: April 24, 2019
Received: April 29, 2019

Dear Homer Trieu:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

FOR CAPT Raquel Peat, PhD, MPH, USPHS
Director
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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K183114

Device Name
Corin BiPolar-i

Indications for Use *(Describe)*
The BiPolar-i is intended for use in the following indications:

- Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis in which the acetabulum does not require replacement,
- Treatment of non-union, femoral neck and trochanteric fractures of the proximal femur
- Revision of failed partial hip replacements in which the acetabulum does not require replacement

The BiPolar-i 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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

## 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 Person:**

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**3. Date:** November 08, 2018

**4. Proprietary Name:** Corin BiPolar-i

**5. Common Name:** Hip Prosthesis

**6. Product Code(s):** KWY

**7. Classification Name:** Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis (21CFR 888.3390)

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

- Primary Predicate Device
  - Corin Bipolar (K925897)
- Secondary Predicate Devices
  - Stryker UHR Universal Bipolar (K800207)
  - Apex Hip System Bipolar Head (K082468)

**9. Device Description:**

The BiPolar-i is a preassembled bipolar head comprised of an ultra-high molecular weight polyethylene (UHMWPE) liner and a highly polished cobalt-chromium alloy (CoCr) outer shell. The BiPolar-i is used in combination with a 22mm or 28mm CoCr modular head (dependent on the BiPolar-i size) and compatible hip stem, both supplied separately. When assembled, the modular head is maintained captive and articulates within the UHMWPE liner. The BiPolar-i is intended for use in partial hip replacement (hemiarthroplasty) to provide increased patient mobility and reduce pain by replacing the natural femoral head and to restore hip joint articulation in patients where there is evidence of a satisfactory natural acetabulum and sufficient femoral bone to seat and support the femoral stem. The BiPolar-i is intended for use with a Corin femoral head and hip stem prosthesis with a compatible 12/14 taper connection and is designed to articulate in the patient's natural acetabulum.

**10. Intended Use:**
The BiPolar-i is intended for use in partial hip replacement (hemiarthroplasty) to provide increased patient mobility and reduce pain by replacing the natural femoral head and to restore hip joint articulation in patients where there is evidence of a satisfactory natural acetabulum and sufficient femoral bone to seat and support the femoral stem.

**11. Indications for Use:**
The BiPolar-i is intended for use in the following indications:

- Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis in which the acetabulum does not require replacement,
- Treatment of non-union, femoral neck and trochanteric fractures of the proximal femur
- Revision of failed partial hip replacements in which the acetabulum does not require replacement

The BiPolar-i is indicated for cementless use only.

**12. Summary of Technologies / Substantial Equivalence:**
The BiPolar-i is identical to the Corin Bipolar (K925897) in terms of material and similar in terms of design, intended use and indications for use. The outer shell size range is similar to that of Corin Bipolar (K925897), Stryker UHR Universal Bipolar (K800207) and Apex Hip System Bipolar Head (K082468). The femoral head sizes which are indicated for use with the Bipolar-i are similar to that of the Stryker UHR Universal Bipolar (K800207) and Apex Hip System Bipolar Head (K082468). Based on these similarities, the BiPolar-i is believed to be substantially equivalent to the predicate devices.

**13. Non-Clinical Testing:**
Non-clinical testing and analysis included pull-out & lever-out force (ASTM F1820-13), assembly testing, range of motion (ISO 21535:2007/Amd1:2016) and evaluation of impingement & wear. The results of these tests show that the Corin BiPolar-i 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.

**14. Clinical Testing:**
Clinical testing was not necessary to determine substantial equivalence between the additional components of the BiPolar-i and the predicate devices.