January 16, 2020

Corin USA Limited
Severine Siracusa
Regulatory Affairs Manager, Corin France
12750 Citrus Park Lane
Tampa, Florida 33625

Re: K191831
Trade/Device Name: MobiliT™ Cup
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, MEH
Dated: December 13, 2019
Received: December 16, 2019

Dear Severine Siracusa:

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,

Vesa Vuniqi
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

2. INDICATIONS FOR USE

510(k) Number (if known): K191831

Device Name: MobiliT™ Cup

Indications for Use:

The MobiliT™ Cup, for cemented and cementless use, are indicated for primary replacement of the hip joint:

- In degenerative pathologies: primary, secondary or post-traumatic osteoarthritis, rheumatoid arthritis
- For patients who have a high risk of dislocation
- In cases of necrosis of the femoral head
- In cases of fracture of the neck of the femur
- In cases of congenital luxation

The MobiliT™ Cup, for cemented and cementless use, are indicated for revision when the bone tissue remains sufficient after the removal of the previous acetabular cup.

The cementless MobiliT™ standard Cup, with flanges or with flanges and hook are indicated for cementless use only.
The cemented MobiliT™ Cup is indicated for cemented use only.

Prescription Use __X____ (Part 21 CFR 801 Subpart D)	AND / OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

3. 510(k) SUMMARY

1. Applicant/Sponsor:
Distributor

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

2. Contact Person:

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3. Date: December 13rd, 2019

4. Proprietary Name: MobiliT™ Cup

5. Common Name: Hip Prosthesis

6. Product Code(s): LZO, MEH

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

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

- Serf, Novae® Dual Mobility Cup (K111572)
- Corin, Trinity Acetabular System (K170359)

9. Device Description:

The MobiliT™ Cup is a modular acetabular system consisting of two articulating surfaces in the same joint space. The MobiliT™ Cup is a metal shell combined with a specific ECiMa™ insert. This system offers two articulating surfaces in the same joint space, one between the shell and the insert, the other between the insert and the femoral head. The shell is made of stainless steel and articulates with ECiMa™ (Vitamin E Ultra-High-Molecular-Weight Polyethylene) insert. A Trinity™ femoral head 22mm or 28mm CoCr, or a 28mm BIOLOX® *delta* articulates within the ECiMa™ insert to allow for a second articulation. The MobiliT™ Cup is designed for use with any Corin 12/14 femoral stem.
The MobiliT™ Cup is intended for use in primary and revision total hip arthroplasty (THA) to provide increased stability and reduce pain by replacing the hip joint articulation where there is evidence of sufficient sound bone to seat and support the components.

The MobiliT™ Cup is intended to be used with the following approved devices:

- 22mm and 28mm CoCr heads (K110087, K131647 and K170359)
- 28mm BIOLOX® *delta* Ceramic Heads (K103120)

10. Intended Use / Indications:

The MobiliT™ Cup, for cemented and cementless use, are indicated for primary replacement of the hip joint:

- In degenerative pathologies: primary, secondary or post-traumatic osteoarthritis, rheumatoid arthritis
- For patients who have a high risk of dislocation
- In cases of necrosis of the femoral head
- In cases of fracture of the neck of the femur
- In cases of congenital luxation

The MobiliT™ Cup, for cemented and cementless use, are indicated for revision when the bone tissue remains sufficient after the removal of the previous acetabular cup.

The cementless MobiliT™ standard Cup, with flanges or with flanges and hook are indicated for cementless use only.
The cemented MobiliT™ Cup is indicated for cemented use only.

11. Summary of Technologies/Substantial Equivalence:

The MobiliT™ Cup is similar to the predicate devices Serf, Novae® Dual Mobility Cup (K111572) and Corin, Trinity Acetabular System (K170359) in terms of design material, size, intended use and indications of use.

Based on these similarities, the MobiliT™ Cup is believed to be substantially equivalent to the predicate devices.

12. Non-Clinical Testing:

Non-clinical testing and analysis for the MobiliT™ Cup conducted to demonstrate substantial equivalence includes Static tests (Push-out, pull-out, lever-out, deformation (ISO7206-12), soaking and dilatation (ASTM D570 & ISO62)) and Dynamic Tests (Range of motion (EN ISO 21535), wear (ISO14242-1/2) and impingement test (ASTM2582-14)).
The results of this tests show that the MobiliT™ Cup is substantially equivalent to the predicate devices.

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 MobiliT™ Cup and the predicate devices.