August 4, 2020

Corin USA
% Martina Cecconi
Regulatory and Clinical Affairs Team Leader
Corin (Australia)
17 Bridge Street
Sydney, 2073 Australia

Re: K193545
Trade/Device Name: Corin Optimized Positioning System (OPS) Femoral
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, LWJ, MEH, PBF
Dated: May 14, 2020
Received: May 15, 2020

Dear Martina Cecconi:

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

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)*
K193545

Device Name
Corin Optimized Positioning System Femoral (Corin OPS™ Femoral)

Indications for Use *(Describe)*
The Corin OPS™ Femoral is intended to be used as a patient-specific surgical instrument to assist the surgeon in delivering a target femoral neck osteotomy, based on a pre-operative plan with implant sizing, type and placement.

The Corin OPS™ Femoral is intended to be used with OPS™ Insight, Corin OPS™ Plan and compatible components. The dislocating Femoral Guide is intended for use with the posterolateral surgical approach and the in-situ Femoral Guide is intended for use with the direct anterior surgical approach.

The Corin OPS™ Femoral PSI is intended for 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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1. 510(K) SUMMARY

1. **Applicant/Sponsor Distributor:**
   Corin USA Limited
   Distributor
   12750 Citrus Park Lane
   Suite 120
   Tampa, Florida 33625
   Establishment Registration No.: 1056629

2. **Manufacturer:**
   Optimized Ortho Pty Ltd
   17 Bridge Street
   Pymble NSW
   2073 Australia
   Establishment Registration No: 3012916784

3. **Contact Person:**
   Crissy Tomarelli
   Regulatory and Quality Director - Australia
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4. **Date:** July 14, 2020

5. **Trade Name:** Corin Optimized Positioning System (OPS™) Femoral

6. **Common Name:** OPS™ Femoral

7. **Classification Product Code(s):** LZO, LWJ, MEH, PBF

8. Classification Name:

21 CFR 888.3353 – Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis.

21 CFR 888.3030 - Orthopaedic Surgical Planning And Instrument Guides.

9. Substantially Equivalent (predicate) device(s):

Primary predicate:

- Corin Optimized Positioning System (OPS™) Femoral (K181061)

Other predicates:

- OPS™ Plan (K171847, K183038) and,
- OPS™ Insight (K192656)

10. Device Description:

The Corin Optimized Positioning System (OPS™) Femoral consists of Femoral Patient Specific Instruments (PSI) and reusable instrumentation. The Femoral Patient Specific Instruments include a Femoral Guide and an optional Trial Femoral Head (Bone Model).

The Femoral Guide is shape-matched to the patient's femoral anatomy and provides a guide for the femoral neck osteotomy during total hip arthroplasty. The planned femoral resection, or target osteotomy, is defined by a preoperative plan (either OPS™ Plan (K171847, K183038) or OPS™ Insight (K192656)). OPS™ Plan and OPS™ Insight are pre-operative tools used by the Surgeon for the selection, sizing and placement of implant components using anatomical landmarks of the femur and pelvis identified from pre-operative CT scan and AP X-ray.

Corin OPS™ Femoral was originally cleared under K181061. The purpose of this submission is to include OPS™ Insight (K192656) to the Indications for Use as an alternative compatible component. The design and

manufacturing process of the device subject of this submission is identical to that of the predicate device K181061.

OPS™ Plan was previously cleared under K171847 and K183038; OPS™ Insight (K192656) is currently under review with FDA. OPS™ Plan (K171847, K183038) and OPS™ Insight (K192656) are not submitted for review in this 510k submission.

11. Indications for Use / Intended Purpose:

The Corin OPS™ Femoral is intended to be used as a patient-specific surgical instrument to assist the surgeon in delivering a target femoral neck osteotomy, based on a pre-operative plan with implant sizing, type and placement.

The Corin OPS™ Femoral is intended to be used with OPS™ Insight, Corin OPS™ Plan and compatible components. The dislocating Femoral Guide is intended for use with the posterolateral surgical approach and the in-situ Femoral Guide is intended for use with the direct anterior surgical approach.

The Corin OPS™ Femoral PSI is intended for single use only.

12. Summary of Technologies/Substantial Equivalence:

The Corin OPS™ Femoral is identical to the primary predicate device Corin OPS™ Femoral (K181061).

The subject device has similar intended uses and indications, technological characteristics, and principles of operation as its predicate device. The differences between the device and its predicate device raise no new issues in terms of safety or effectiveness.

Device comparison showed that the proposed device is substantially equivalent in intended use, technology, material and performance characteristics to the predicate devices.

The subject device works with predicate preoperative plans, OPS™ Plan (K171847, K183038) and OPS™ Insight (K192656)

13. Non-Clinical Testing:

Non-clinical testing was performed to assess the safety and effectiveness of the device.

Testing included quantitative assessments of clinical accuracy, biocompatibility and dimensional stability. Packaging, distribution, cleaning and sterilization validation of the OPS™ Femoral PSI was completed.

Testing verified that the accuracy and performance of the device is adequate to perform as intended.

14. Clinical Testing:

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

15. Conclusion:

The subject device has similar intended uses and indications, and technological characteristics, and material as its predicate device. The differences between the device and its predicate device raise no new issues in terms of safety or effectiveness.