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

July 22, 2019

Re: K190834
Trade/Device Name: Corin Optimized Position System Functional Hip Analysis (OPS FHA)
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, PLW, MEH, LWJ
Dated: June 19, 2019
Received: June 20, 2019

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,

FOR 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)*
K190834

Device Name
Corin Optimized Positioning System Functional Hip Analysis (OPS™ FHA)

Indications for Use *(Describe)*
The Corin Optimized Positioning System Functional Hip Analysis (OPS™ FHA) is indicated for preoperative analysis of primary total hip arthroplasty. Corin OPS™ FHA is intended to be used as a pre-operative tool which provides the Surgeon with functional acetabular cup orientations based on the patient pelvic kinematics and presents a visualisation of the patient's hemipelvis.

The Corin OPS™ FHA is intended for use with the Corin Trinity Acetabular System (K093472, K110087, K111481, K122305, K123705, K130128, K130343 and K131647) for total hip arthroplasty.

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.

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510 (K) SUMMARY

Applicant/Sponsor	Corin USA Limited
Distributor:	Distributor 12750 Citrus Park Lane Suit 120 Tampa, Florida 33625 Establishment Registration No: 1056629
Manufacturer	Optimized Ortho Pty Ltd 17 Bridge Street Pymble NSW 2073 Australia Establishment Registration No: 3012916784
Contact Person	Martina Cecconi Regulatory and Clinical Affairs Team Leader Corin (Australia Pty Limited Martina.Cecconi@coringroup.com Lucina Gerber Global Regulatory Affairs Manager Corin USA Limited 1 (772) 321-2478 Lucinda.Gerber@coringroup.com

Date: 29 March 2019

Trade name: Corin Optimized Positioning System Functional Hip Analysis (OPS™ FHA)

Common name: Hip Prosthesis

Classification product code(s): LZO

Additional Product Code(s): MEH, LWJ, PLW

Classification name:

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

Additional Classification Names:

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

Substantially Equivalent (predicate) device(s):

- Corin Optimized Positioning System (OPS™) (K152893)

Device description

The Corin Optimized Positioning System Functional Hip Analysis (OPS™ FHA) consists of a pre-operative patient specific analysis and two patient specific reports: Functional Hip Analysis (FHA) report and Patient Specific Visualisation (PSV) report.

The Corin OPS™ FHA assists the surgeon in determining a patient specific target orientation for the acetabular cup using anatomical landmarks of the pelvis obtained from pre-operative CT scan and X-ray data and a subsequent functional pelvic kinematic analysis (FHA report), and visualisation of the patient's 3-dimensional anatomy (PSV report).

Corin Optimized Positioning System (OPS™) K152893 consists of FHA and PSV reports provided preoperatively and Patient Specific Instruments and Reusable instrumentation components for intraoperative use to assist the surgeon in the alignment of prosthetic components during total hip arthroplasty.

The purpose of this submission is to separate and create a new submission for the components, FHA and PSV reports. The FHA and PSV reports are the same components, part of the Corin Optimized Positioning System (OPS™) which was a previously cleared in K152893.

Indications for use / intended purpose:

The Corin Optimized Positioning System Functional Hip Analysis (OPS™ FHA) is indicated for preoperative analysis of primary total hip arthroplasty. Corin OPS™ FHA is intended to be used as a pre-operative tool which provides the Surgeon with functional acetabular cup orientations based on the patient pelvic kinematics and presents a visualisation of the patient's hemipelvis.

The Corin OPS™ FHA is intended for use with the Corin Trinity Acetabular System (K093472, K110087, K111481, K122305, K123705, K130128, K130343 and K131647) for total hip arthroplasty.

Summary of technologies / substantial equivalence:

The Corin OPS™ FHA is identical to the predicate device Corin OPS™ (K152893) with the exception that no hardware components are part of the subject of this submission.

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

Non-clinical testing:

Non-clinical testing was performed to assess the safety and effectiveness of the device., Reproducibility and Repeatability study was performed to demonstrate that the process used to generate FHA report is reliable and repeatable.

Clinical testing:

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

Conclusion:

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 devices raise no new issues in terms of safety or effectiveness.