Corin USA Limited
% Ms. Martina Cecconi
Regulatory and Clinical Affairs Team Leader
12750 Citrus Park Lane, Suite 120
TAMPA FL 33625

April 5, 2018

Re: K171847
Trade/Device Name: Corin Optimized Positioning System (OPS™) Plan
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ, LZO, MEH
Dated: March 20, 2018
Received: March 22, 2018

Dear Ms. 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. 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); 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.

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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)*
K171847

Device Name
Corin Optimized Positioning System (OPS™) Plan

Indications for Use *(Describe)*
The Corin Optimized Positioning System Plan (OPS™ Plan) is indicated for pre-operative planning for primary total hip arthroplasty. OPS™ Plan is intended to be used as a pre-operative tool to assist the Surgeon in the selection (for example, lateralised or standard stem), sizing and positioning of components of primary total hip arthroplasty.

The Corin OPS™ Plan is intended to be used with the Corin TriFit TS (K121563, K153772), MetaFix (K082525, K121439, K131952, K153381), TaperFit (K142761, K153725), MiniHip (K083312, K11046, K131986) Femoral Hip Stems.

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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3.2 510(K) SUMMARY

1. **Applicant/Sponsor:** 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:** Martina Cecconi

   Regulatory and Clinical Affairs Team Leader

   Corin Australia

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   Lucinda Gerber

   Global Regulatory Affairs Manager

   Corin USA Limited

   1 (772) 321-2478

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4. **Date:** March 20, 2018

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

6. **Common Name:** Image Processing Software

7. **Classification Product Code(s):** LLZ

   Additional Product Code(s): LZO, MEH

8. **Classification Name:** 21 CFR 892.2050 – Picture archiving and communications

Additional Classification Names:

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

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

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

- ZedView (K133022)

10. Device Description:

The Corin Optimized Positioning System™ Plan (OPS™ Plan) is a pre-operative templating tool to assist the Surgeon in the planning of primary total hip arthroplasty using any Corin femoral stem. The Corin OPS™ Plan assists in selection (for example, lateralised or standard stem), sizing and placement of implant components (stem, head, cup) using anatomical landmarks of the femur and pelvis obtained from pre-operative CT scan and AP X-ray. The OPS™ Plan report is a static report which displays the selection (for example, lateralised or standard stem), sizing and placement of implant components.

The Corin OPS™ Plan process begins with booking the OPS case to final release of the OPS Plan Report. OPS™ case booking details and required CT and X-ray imaging in DICOM format are electronically transferred to the manufacturer via the online end-user interface, the OPS™ Portal. Image processing is completed by an OPS™ Simulation Engineer with results of the OPS™ analysis provided in the OPS™ Plan Report. The Surgeon does not actively interact with the image processing, implant positioning and/or report generation. Final acceptance of the OPS™ Plan by the Surgeon is confirmed following any modifications or clarifications of the reported results.

11. Indications for Use / Intended Purpose:

The Corin Optimized Positioning System Plan (OPS™ Plan) is indicated for pre-operative planning for primary total hip arthroplasty. OPS™ Plan is intended to be used as a pre-operative tool to assist the Surgeon in the selection (for example, lateralised or standard stem), sizing and positioning of components of primary total hip arthroplasty.

The Corin OPS™ Plan is intended to be used with the Corin TriFit TS (K121563, K153772), MetaFix (K082525, K121439, K131952, K153381), TaperFit (K142761, K153725), MiniHip (K083312, K11046, K131986) Femoral Hip Stems.

12. Summary of Technologies/Substantial Equivalence:

The device comparison showed that the subject device is substantially equivalent to the predicate in that both have similar indications for use as a pre-operative surgical planning tool for total hip replacement. The subject device and predicate device have similar technological characteristics and principles of operation with both utilizing CT scans to generate 3D patient specific bone models which enables 3D implant templating for surgical planning and X-ray imaging to identify boney landmarks. The subject device differs from the predicate in that the Surgeon cannot actively generate, alter or change the surgical pre-plan and must communicate any desired changes to the manufacturer so that the OPS™ Simulation Engineer and make the requested changes to the pre-operative plan. The final end user in both the subject and predicate devices is the Surgeon. The subject device is used for total hip replacement while the predicate can be used for pre-operative planning for both total hip and total knee replacement.

13. Non-Clinical Testing:

Non-clinical testing was performed to assess the safety and effectiveness of the device, to demonstrate the processing of patient imaging to produce accurate, repeatable and reproducible implant selection, sizing and placement of components, and the usability of the OPS™ Plan that is provided to the Surgeon. Testing verified that the accuracy and performance of the system 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 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.