June 26, 2020

Corin USA
% Ms. Martina Cecconi
Regulatory and Clinical Affairs Team Leader
Corin (Australia)
17 Bridge Street
Sydney, New South Wales 2073
AUSTRALIA

Re: K193042
Trade/Device Name: Optimized Positioning System (OPS) ReView
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ, LZO, MEH, LWJ, PLW
Dated: June 9, 2020
Received: June 10, 2020

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. 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,

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
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)*
K193042

Device Name
Optimized Positioning System (OPS) ReView

Indications for Use *(Describe)*
OPSReView™ is intended to be used as a postoperative tool for visualising and quantifying component alignment to aid in the analysis of hip alignment following hip replacement surgery.
OPSReView™ provides the surgeon with information relating to the in-situ implant placement as well as associated functional analysis and 3D biomechanical measurements, based on landmarks derived from patient specific postoperative imaging.

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

K193042

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:** Crissy Tomarelli
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   Lucinda Gerber
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   Corin USA Limited
   1 (772) 321-2478
   Lucinda.Gerber@coringroup.com

4. **Date:** Tuesday, June 9, 2020

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

6. **Common Name:** OPSReView™

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

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

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 888.3350 - Hip joint metal/polymer semi-constrained cemented Prosthesis

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

- Eos Imaging SterEOS Workstation (K172346).
- Corin OPS™ Plan (K171847, K183038).
- Corin OPS™ FHA (K190834)

10. Device Description:

OPSReView™ is an image analysis tool that provides surgeons with post-operative information regarding the femoral stem and acetabular cup orientations and patient pelvic parameters following hip replacement surgery. OPSReView™ is provided to the surgeon in the form of a static PDF report that displays the results of the analysis and uses post-operative CT and X-ray imaging as inputs.

The information provided in the OPS™ ReView report includes the patient's pelvic parameters, in-situ implant measurement describing the in-situ implant placement and post-operative radiographic images.

The implant parameters, including 3D geometry and associated landmarks, required to calculate the in-situ implant measurements are contained within a controlled database.

11. Indications for Use / Intended Purpose:

OPSReView™ is intended to be used as a postoperative tool for visualising and quantifying component alignment to aid in the analysis of hip alignment following hip replacement surgery.

OPSReView™ provides the surgeon with information relating to the in-situ implant placement as well as associated functional analysis and 3D biomechanical measurements, based on landmarks derived from patient specific postoperative imaging.

12. Summary of Technologies/Substantial Equivalence:

The device comparison showed that the subject device is substantially equivalent to the predicate the EOS Imaging SterEOS Workstation (K172346), Corin OPS™ Plan (K171847, K183038) and Corin OPS™ FHA (K190834). The subject device and SterEOS Workstation (K172346) can both be used as a postoperative tool to provide an image-based analysis and associated measurements of a patient's hip. The subject device and Corin OPS™ Plan (K171847, K183038) can both be used as tool to provide an image-based analysis of a patient's hip. The subject device and the Corin OPS™ FHA (K190834) both provide calculated outputs of the hip joint during functional activities and information about functional orientation of the acetabular cup.

The subject device and predicate devices EOS Imaging SterEOS Workstation (K172346), Corin OPS™ Plan (K171847, K183038) and Corin OPS™ FHA (K190834), have similar technological characteristics and principles of operation, all utilizing imaging scans to generate a patient specific report. The end user for the subject and predicate devices are trained medical professionals and the subject and predicate devices do not have contact with the patient. Based on these similarities, Corin believes that the OPS™ ReView is substantially equivalent to the predicate devices.

13. Non-Clinical Testing:

Non-clinical testing was performed to assess the accuracy of the device, the usability of the OPS™ ReView report provided to the Surgeon, and to demonstrate that the software utilized in the device functions as intended.

14. Clinical Testing:

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

15. Conclusion:

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