Corin USA
% Crissy Tomarelli
Regulatory and Quality Director
Corin (Australia)
17 Bridge Street
Sydney, New South Wales 2073
AUSTRALIA

November 20, 2020

Re: K202805
Trade/Device Name: Optimized Positioning System (OPS) Insight™
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving And Communications System
Regulatory Class: Class II
Product Code: LLZ
Dated: September 22, 2020
Received: September 23, 2020

Dear Crissy Tomarelli:

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 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or post marketing 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

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)* K202805

Device Name
Optimized Positioning System (OPS) Insight™

Indications for Use *(Describe)*
OPSInsight™ is intended for use as preoperative surgical planning software to aid orthopaedic surgeons in component selection, sizing and placement for primary 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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5. 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:**

   Crissy Tomarelli
   Regulatory and Quality Director
   Corin Australia
   +61 (0)2 94977400
   Crissy.Tomarelli@coringroup.com

   Jack Liang
   Senior Regulatory Affairs Specialist
   Corin Australia
   +61 (04) 21135848
   Jack.Liang@coringroup.com

4. **Date:** 22nd September 2020

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

6. **Common Name:** OPSInsight™ or OPSInsight

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

8. Classification Name:

- 21 CFR 892.2050 – Picture archiving and communications

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

- Optimized Positioning System (OPS™) Insight (K192656)

10. Device Description:

OPSInsight™ is an interactive software for preoperative planning of Total Hip Arthroplasty. It enables 3D sizing and placement of implants in the patient's anatomy, calculates biomechanical measurements and performs functional analysis based on landmarks and anatomical models derived from patient-specific radiographic imaging and the templated implants. The biomechanical measurements include measurements relating to leg length, offset and femoral version, and the functional analysis includes determination of pelvic parameters, cup orientation calculation during flexion and extension, and impingement detection.

The software uses 2D and 3D patient-specific radiographic data. The implant data required by the software is contained within a controlled database. OPSInsight™ is a closed platform. Please refer to the Instructions for Use for compatible implant systems.

11. Indications for Use / Intended Purpose:

OPSInsight™ is intended for use as preoperative surgical planning software to aid orthopedic surgeons in component selection, sizing and placement for primary total hip arthroplasty.

12. Summary of Technologies/Substantial Equivalence:

The subject device and predicate device have the same indications for use, technological characteristics and principles of operation, both utilizing the same imaging protocol to generate an interactive preoperative plan. The predicate outputs the same biomechanical measurements (including those relating to leg length, offset and femoral version, cup orientation), performs

the same functional analysis of spinopelvic parameters and functional cup orientation calculations, and performs the same prosthetic impingement detection as the subject device. The end user for both the subject and predicate devices are orthopedic surgeons. The subject and predicate devices do not contact the patient.

The subject device differs from the predicate device in that the subject device also includes a bony impingement detection feature.

The differences between the subject device and its predicate device raise no new issues in terms of safety or effectiveness. Therefore, based on these similarities, Corin believes that the OPSInsight is substantially equivalent to the predicate device.

13. Non-Clinical Testing:

Non-clinical testing was performed, assessing the usability and performance testing that was conducted on the predicate device. In addition to this, non-clinical testing was performed to assess the performance of the bony impingement feature in OPSInsight to demonstrate that the feature functions as intended. Software verification and validation testing was conducted according to IEC 62304 and documentation provided as recommended by FDA's Guidance for the Industry: 'Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.'

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.