Orthosoft d/b/a Zimmer CAS
℅ Mr. Paul Hardy
Regulatory Affairs Associate Director
75 Queen Street, Suite 3300
Montreal, Quebec H3C 2N6
CANADA

July 7, 2021

Re: K210653
Trade/Device Name: ONE Planner™ Hip
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical imaging management and processing system
Regulatory Class: Class II
Product Code: LLZ, LZO, PBI, LPH
Dated: May 25, 2021
Received: June 1, 2021

Dear Mr. Hardy:

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 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

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)*
K210653

Device Name
ONE Planner™ Hip

Indications for Use *(Describe)*
ONE Planner™ Hip is intended for use as preoperative surgical planning software to aid orthopedic 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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# 510(k) Summary

In accordance with 21 CFR §807.92 and the Safe Medical Devices Act of 1990, the following information is provided for the ONE Planner™ Hip 510(k) premarket notification. The submission was prepared in accordance with the FDA guidance document, 'Format for Traditional and Abbreviated 510(k)s', issued on September 13, 2019.

**Sponsor :**

Orthosoft, Inc. (d/b/a Zimmer CAS)
75 Queen St., Suite 3300
Montreal, QC, CANADA H3C 2N6
Establishment Registration Number: 9617840

**Contact Person(s):**

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Dave Bierhuizen
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Dave.Bierhuizen@zimmerbiomet.com

**Date:**

June 29, 2021

**Subject Device:**

**Trade Name:** ONE Planner™ Hip
**Common Name:** Image Processing System

**Product Code(s) / Classification Name (s):**

- LLZ - Picture Archiving and Communications System to Medical imaging management and processing system (21 CFR 892.2050).
- LZO – Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (21 CFR 888.3353)
- PBI - Hip joint metal/polymer constrained cemented or uncemented prosthesis (21 CFR 888.3310)
- LPH- Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis (21 CFR 888.3358

**Predicate Device(s):**

| Manufacturer | Device Name | 510(k) Number |
|---|---|---|
| Corin | Corin Optimized Positioning System Insight | K192656 |

**Purpose and Device Description:**

ONE Planner™ Hip (OPH) is an interactive software application intended to be used as a preoperative tool for Total Hip Arthroplasty. It enables 2D sizing and positioning of implants in the patient's anatomy, calculates biomechanical measurements and performs functional analysis based on the patient's pelvic kinematics. The biomechanical measurements include measurements related to leg length and femoral offset. The functional analysis includes determination of pelvic parameters (e.g. pelvic tilt), and cup orientation calculations.

The software application consists of an automated templating system and a web-based templating user interface.

**Indications for Use:**

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

**Summary of Technological Characteristics:**

The rationale for substantial equivalence is based on consideration of the following characteristics:

- **Indications for Use:** ONE Planner™ Hip and the predicate device have the same Indications for Use.
- **Design Features:** Both devices have the following features:
  - ONE Planner™ Hip and the predicate device use input files consisting of X-ray images.
  - ONE Planner™ Hip and the predicate device provide image processing tools.
  - ONE Planner™ Hip and the predicate device provide preoperative sizing values.
  - ONE Planner™ Hip and the predicate device provide functional analysis of pelvic parameters
  - ONE Planner™ Hip and the predicate device provide interactive adjustment of the preoperative surgical plan
  - ONE Planner™ Hip and the predicate device provide tools for visualization and to perform measurements, and to choose size and position implants.
  - ONE Planner™ Hip and the predicate device export a preoperative surgical plan.

**Compatible Devices:**

ONE Planner™ Hip can be used with the following implant systems:

G7 Acetabular Systems (K121874, K142746, K142882, K140669, K150522, K190660, K190656)
Taperloc Complete Stems (K101086, K103755, K110400, K120030, K200196)

Echo Bi-Metric Stems (K070274, K143009, K150503)
Avenir Complete (K182048, K192189)
Avenir Muller and Cemented Hip Stems (K123392, K131884, K193030)

**Summary of Performance Data (Nonclinical and/or Clinical):**

ONE Planner™ Hip has been evaluated through the following non-clinical testing:

- **Software Verification & Validation Testing**
  Software verification and validation testing was conducted to satisfy the requirements of the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices and IEC 62304 (Medical Device Software- Life Cycle Process). The software is considered a "moderate" level of concern, a malfunction in the device could lead to a minor injury. The testing demonstrates that the ONE Planner™ Hip does not introduce new questions of safety and effectiveness as compared to the predicate device.

- **Non-Clinical Testing**
  Non-clinical testing was performed to assess the usability and performance of the ONE Planner™ Hip to demonstrate that the device functions as intended.

- **Clinical Testing**
  Clinical testing was not necessary for the determination of substantial equivalence.

**Substantial Equivalence Conclusion:**

The subject device has the same intended use, same indications for use, similar technological characteristics and principles of operation as the predicate device. The differences between the subject device and the predicate device does not introduce new types of safety and effectiveness questions. Therefore, the subject device is at least as safe and effective as the legally marketed predicate device.