Orthosoft, Inc. (d/b/a Zimmer CAS)
Paul Hardy
Sr. Regulatory Specialist
75 Queen St., Suite 3300
MONTREAL, QC, H3C 2N6
CANADA

August 23, 2019

Re: K183544
Trade/Device Name: Efficient Care 3D Planning
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving and Communications System
Regulatory Class: Class II
Product Code: LLZ
Dated: July 22, 2019
Received: July 23, 2019

Dear Paul 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); 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K183544

Device Name
Efficient Care 3D Planning

Indications for Use *(Describe)*

Efficient Care 3D Planning is software indicated for assisting orthopedic surgeons in preoperative planning of knee orthopedic surgeries. The software allows for the overlaying of 3D/2D implant models and for the visualization of the radiological images and 3D reconstruction of bones, and includes tools for performing measurements on the images or 3D model of bones, and for selecting and positioning the implant model. Clinical judgments and experience are required to properly use the software.

Efficient Care 3D Planning is to be used with the following fixed bearing knee replacement systems in accordance with their indications and contraindications: NexGen® CR, NexGen CR-Flex, NexGen CR-Flex Gender, NexGen LPS, NexGen LPS-Flex, NexGen LPS-Flex Gender, Persona® CR, Persona PS, Vanguard® CR, and Vanguard PS.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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 Efficient Care 3D Planning 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 August 12, 2005.

Sponsor:

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

Contact Person:

Paul Hardy
Regulatory Affairs Sr. Specialist
Telephone: 574-372-6799

Date:

August 19, 2019

Subject Device:

Trade Name: Efficient Care 3D Planning
Common Name: Image Processing System

Classification Name:

- LLZ-Picture Archiving and Communications System (21 CFR 892.2050)

Predicate Device(s):

Manufacturer	Device Name	510(k) Number
ONEFIT medical, Inc.	kneeEOS	K161828

Purpose and Device Description:

Efficient Care 3D Templating is software application that is intended to assist in the preoperative sizing of femoral and tibial implants. The software solution allows for the processing of multiple 2D X-rays to create 3D bone models that scales to patient bones and compensates for patient leg rotation in the X-rays images. The 3D bone

models allow implant sizing to occur and output a template report, which includes overlays of prostheses, in respect to leg orientations on the X-ray images. Final implant sizing is based on intraoperative surgeon assessment.

Indications for Use:

Efficient Care 3D Planning is software indicated for assisting orthopedic surgeons in preoperative planning of knee orthopedic surgeries. The software allows for the overlaying of 3D/2D implant models and for the visualization of the radiological images and 3D reconstruction of bones, and includes tools for performing measurements on the images or 3D model of bones, and for selecting and positioning the implant model. Clinical judgments and experience are required to properly use the software.

Efficient Care 3D Planning is to be used with the following fixed bearing knee replacement systems in accordance with their indications and contraindications: NexGen® CR, NexGen CR-Flex, NexGen CR-Flex Gender, NexGen LPS, NexGen LPS-Flex, NexGen LPS-Flex Gender, Persona® CR, Persona PS, Vanguard® CR, and Vanguard PS.

Summary of Technological Characteristics:

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

- **Indications for Use:** Efficient Care and the predicate device have similar indications for uses.
- **Design Features:** Both software packages have the following features:
  - Efficient Care and the predicate device utilize x-ray image(s) for image segmentation and processing
  - Efficient Care and the predicate device provide the capability to visualize 3D models of the bone
  - Efficient Care and the predicate device provide preoperative sizing values
  - Efficient Care and the predicate device provide tools to improve visualization, perform implant measurements to choose, size and position the implant
  - Efficient Care and the predicate device export a PDF planning report for surgeon review

Summary of Performance Data (Nonclinical and/or Clinical)

Efficient Care has been evaluated through the following non-clinical testing

- **Implant Predictability Tests**
  The objective of these tests were to confirm that the Efficient Care device could accurately predict the correct implant size within ±2 sizes in 90% of cases when the magnification sphere object is present and to evaluate the accuracy of the system quantitatively. The predicted pre-op implant size was compared to the post-op implant size to assess the performance of the size evaluation aspect of the Efficient Care device.

- **Biocompatibility Testing**
  The biocompatibility evaluation for Efficient Care was conducted in accordance with ISO 10993. The evaluation reveals that the Efficient Care device meets biocompatibility requirements.

- **Software Verification & Validation Testing**
  Testing was conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices". The software was considered as a "moderate level of concern", since a failure or latent design flaw could lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury.

Substantial Equivalence Conclusion

The subject device has the same intended use, similar indications for use, 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 proposed device is at least as safe and effective as the legally marketed predicate device.