January 14, 2022

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

Re: K213033
Trade/Device Name: iASSIST Knee System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: September 20, 2021
Received: September 21, 2021

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,

Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma Devices
OHT6: Office of Orthopedic Devices
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)*
K213033

Device Name
iASSIST® Knee System

Indications for Use *(Describe)*
The iASSIST Knee System is a computer assisted stereotaxic surgical instrument system intended to assist the surgeon in preparing the bone surfaces for the positioning of orthopedic implant system components intra-operatively. It involves surgical instruments and inertial sensors to determine alignment axes in relation to anatomical landmarks and to precisely position alignment instruments and cut guides relative to these axes.

The present iASSIST Knee System is designed for Total Knee 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.

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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 iASSIST® Knee System 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:

Paul Hardy
Regulatory Affairs Associate Director
Telephone: 574-453-6739
Paul.Hardy@zimmerbiomet.com

Date:

January 5, 2022

Subject Device:

Trade Name: iASSIST® Knee System
Common Name: iASSIST® Knee System

Classification Name:

- OLO– Orthopedic Stereotaxic Instrument (21 CFR 882.4560)

Primary Predicate Device:

Manufacturer	Device Name	510(k) Number
Zimmer CAS	iASSIST Knee System	K192080

Reference Devices:

Manufacturer	Device Name	510(k) Number
Zimmer CAS	iASSIST Knee System	K141601
Zimmer CAS	SmartTools Knee System	K122326

Purpose and Device Description:

As in the predicates, the iASSIST Knee System consists of Pods (tracking sensors), a computer system, software, and surgical instruments designed to assist the surgeon in the placement of Total Knee Replacement components. The Pods combined with the surgical instruments provide positional information to help orient and locate the main femoral and tibial cutting planes as required in knee replacement surgery. This includes means for the surgeon to determine and thereafter track each of the bones' alignment axes relative to

which the cutting planes are set. The computer system and software components control and sequence the functions of the Pods per the applicable knee surgery steps via wireless communication.

Indications for Use:

The iASSIST Knee System is a computer assisted stereotaxic surgical instrument system intended to assist the surgeon in preparing the bone surfaces for the positioning of orthopedic implant system components intra-operatively. It involves surgical instruments and inertial sensors to determine alignment axes in relation to anatomical landmarks and to precisely position alignment instruments and cut guides relative to these axes.

The present iASSIST Knee System is designed for Total Knee Arthroplasty.

Summary of Technological Characteristics:

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

- The subject and predicate devices are intended to assist the surgeon in providing software defined spatial boundaries for orientation
- The subject and predicate devices assist in intraoperative navigation of the patient's anatomy and are utilized to facilitate implant positioning.
- The subject and predicate device consists of the same major components including Pods, Surgical Instruments, iASSIST V2 Tablet and software components.
- The software and iASSIST V2 Tablet of the subject and predicate devices are intended to sequence and to control the Pods and their user interface functions via wireless communication.
- The software algorithm and instrument features of the subject and predicate devices are intended to determine and track the alignment axes to reference the cutting planes.
- The instrument features and functions of the subject and predicate devices are intended to allow assembly of the sensors, to attach the subject bones, to register or digitize the applicable landmarks, and to adjust the alignment of provided saw guides.

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

The iASSIST® Knee System has been evaluated through the following non-clinical testing in support of the substantial equivalence determination:

Device Performance Testing:

Verification and Validation Testing for iASSIST Knee System was conducted with the following aspects:

- Physical/Performance Tests- to ensure the performance of the implemented features and verify related design inputs
- Engineering Analysis- to ensure the performance of the implemented features and verify related design inputs
- Usability Engineering- addressed user interactions with the iASSIST Knee System
- Validation Lab- performed to validate that using the iASSIST Knee System is safe and effective and that the performances of the iASSIST Knee System are acceptable under full simulated use on cadaveric specimens

Software Verification and Validation Testing:

Software tests were 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 iASSIST Knee System does not raise any new issues of safety and effectiveness as compared to the predicate devices.

Substantial Equivalence Conclusion:

In summary, the subject and predicate devices have similar indications for use, the same intended use, the same principle of operation as well as similar technological characteristics. Furthermore, the information provided herein demonstrates that:

- Any differences do not raise new questions of safety and effectiveness;
- Verification and Validation activities demonstrate that the subject device is at least as safe and effective as the legally marketed predicate devices.