June 13, 2023

Orthosoft Inc. (d/b/a Zimmer CAS)
Mona Mansouri
Regulatory Affairs Senior Specialist
75 Queen Street Suite 3300
Montreal, Quebec H3C 2N6
Canada

Re: K230567
Trade/Device Name: OptiVu™ ROSA® MxR
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO, LLZ
Dated: March 14, 2023
Received: March 15, 2023

Dear Mona Mansouri:

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,

FDA Tejen D. Soni -S
2023.06.13
17:15:32 -04'00'

For
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)*
K230567

Device Name
OptiVu™ ROSA® MxR

Indications for Use *(Describe)*
OptiVu™ ROSA® MxR is indicated for displaying surgical workflow images from the ROSA® RECON platform in Mixed Reality. It includes functions for viewing the same surgical workflow steps and 2D visualizations as presented on the existing ROSA RECON platform user interface. When accessing ROSA® MxR from a stereoscopic head mounted display (HMD), images viewed are for informational purposes only and are not intended for diagnostic use.

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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K230567

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 OptiVu™ ROSA® Mixed Reality 510(k) premarket notification. The submission was prepared in accordance with the FDA guidance document, *The Special 510k Program, Guidance for Industry and Food and Drug Administration Staff*, 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:

Mona Mansouri
Regulatory Affairs Sr. Specialist
Telephone: (647-637-8950)
Mona.Mansouri@zimmerbiomet.com

Date:

February 28, 2023

Subject Device:

Trade Name: OptiVu™ ROSA® MxR
Common Name: OptiVu™ ROSA® Mixed Reality

Classification Name:

- OLO– Orthopedic Stereotaxic Instrument (21 CFR 882.4560)
- LLZ- Medical Image Management and Processing System (21 CFR 892.2050)

Predicate Device:

510(k) Number	Device Name	Manufacturer	Predicate
K220733	OptiVu™ ROSA® MxR	Zimmer CAS	Primary

Purpose and Device Description:

OptiVu™ ROSA® Mixed Reality (ROSA® MxR) is indicated for displaying surgical workflow images from the ROSA® RECON Platform and the corresponding ROSA® clinical applications intra-operatively during orthopedic surgeries. It is intended to provide an additional means of display where the ROSA® RECON Platform user interface is duplicated into a Mixed

Reality see-through environment. OptiVu™ ROSA® MxR allows the ROSA® RECON Platform user interface and corresponding ROSA® clinical applications (ROSA Knee, ROSA Partial or ROSA Hip) to be streamed through a compatible head-mounted display (HMD) (e.g. HoloLens 2).

The subject device's main purpose is to place the duplicated virtual ROSA® user interface at a convenient location to provide the following functionalities:

- Mixed Reality visualization solution
- Wireless connectivity between a HMD (e.g. HoloLens 2) and the ROSA® RECON Platform
- Interaction with the duplicated user interface and RECON Platform (e.g. voice, eye gaze and hand gestures)

Indications for Use:

OptiVu™ ROSA® MxR is indicated for displaying surgical workflow images from the ROSA® RECON platform in Mixed Reality. It includes functions for viewing the same surgical workflow steps and 2D visualizations as presented on the existing ROSA RECON platform user interface. When accessing ROSA® MxR from a stereoscopic head mounted display (HMD), images viewed are for informational purposes only and are not intended for diagnostic use.

Summary of Technological Characteristics:

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

- **Intended Use:** Same as predicate device
- **Indications for Use:** Same as predicate device
- **Principles of Operation**: Same as predicate device
- **Mixed Reality functions:** Similar to predicate device it utilizes an off-the-shelf HMD (e.g. HoloLens 2) to stream images with the ability for additional interaction with the user interface and ROSA RECON platform.

Summary of Performance Data (Nonclinical and/or Clinical)

Non-Clinical Tests:

A subsequent performance and integration test was performed regarding the active command functions and is described in the *Section 11- Design Control Activities Summary.*

Substantial Equivalence Conclusion:

The proposed and predicate device have the same intended use and the same principles of operation. The modifications to the proposed device do not alter the Indications for Use or the fundamental technology. In sum, any differences between the devices does not raise new questions of safety and effectiveness and the proposed device is at least as safe and effective as the legally marketed predicate device.