July 29, 2022

Orthosoft, Inc. (d/b/a Zimmer CAS)
Paul Hardy
Associate Director
75 Queen St., Suite 3300
Montreal, QC H3C 2N6
Canada

Re: K220733
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: April 27, 2022
Received: May 2, 2022

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: 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)*
K220733

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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K220733
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® MxR 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, H3C 2N6, CANADA
Establishment Registration Number: 9617840

Contact Person:

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

Date:

July 29th, 2022

Subject Device:

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

Classification Name:

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

Predicate Device(s):

510(k) Number	Device Name	Manufacturer	Predicate
K182964	ROSA® Knee System	Zimmer CAS	Primary
K200384	HipXpert System	Surgical Planning Associates, Inc.	Reference

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 (e.g. 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
- Register hand gestures as inputs such as to touch, move and resize views
- Wireless connectivity between a HMD (e.g. HoloLens 2) and the ROSA® RECON Platform

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:

- The proposed device and the primary predicate share the same previously cleared ROSA® RECON Platform hardware (robotic and optical unit) and the same previously cleared ROSA® RECON Platform software (OS, SDK Software, and Case Management software).

- The proposed device has similar principles of operation as the predicate devices. OptiVu™ ROSA® MxR and the secondary predicate both utilize an off-the-shelf HMD (e.g. HoloLens 2) to stream images pertaining to surgical procedures for intra-operative use. The encrypted images streamed through the HMD (e.g HoloLens 2) allows the surgeon to view the display in a Mixed Reality environment. OptiVu™ ROSA® MxR and the secondary predicate device both display surgical workflow images. The ROSA® Knee System displays the workflow through its hardware component, the ROSA® RECON Platform whereas OptiVu™ ROSA® MxR connects through wifi to the ROSA®

RECON Platform to stream a duplicate of the ROSA® RECON Platform user interface in Mixed Reality in real-time. The proposed device does not perform any pre-operative surgical planning as compared to the primary predicate device. The proposed device does not provide the viewing of images in 3D as compared to the secondary predicate.

Summary of Performance Data (Nonclinical and/or Clinical)

The following performance data was provided in support of the substantial equivalence determination:

Device Performance Testing

Verification and Validation Testing for OptiVu™ ROSA® MxR 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 OptiVu™ ROSA® MxR

Software Verification and Validation Testing

Software tests were conducted to satisfy requirements of the FDA Guidance for the Content Premarket Submissions for Software Contained in Medical Devices and IEC 62304 (Medical Device Software- Life Cycle Process). The software was considered a "major" level of concern, since OptiVu™ ROSA® MxR is an accessory to a medical device that has a major level of concern. The testing demonstrates that OptiVu™ ROSA® MxR does not raise any new issues of safety and effectiveness as compared to the predicate device(s).

Substantial Equivalence Conclusion

The proposed device and the primary predicate device share the same previously cleared ROSA® RECON Platform hardware (robotic and optical unit) and the same previously cleared ROSA® RECON Platform software (OS, SDK Software, and Case Management software).

In addition, the proposed device has similar principles of operation as the predicate devices. The proposed device utilizes an off-the-shelf HMD (e.g. HoloLens 2) to stream images pertaining to surgical procedures for intra-operative use which is the same as the secondary predicate device. The proposed device does not perform any pre-operative surgical planning as compared to the primary predicate. The proposed device does not provide the viewing of images in 3D as compared to the secondary predicate.

In summary, differences between the devices do 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(s).