Xironetic, LLC
% Elaine Duncan
President
Paladin Medical, Inc
PO Box 560
STILLWATER MN 55082

Re: K213128

October 21, 2022

Trade/Device Name: IntraOpVSP Software Device
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: September 15, 2022
Received: September 21, 2022

Dear Elaine Duncan:

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,

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software Team
DHT8B: Division of Radiological Imaging Devices and Electronic Products
OHT8: Office of 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: 0MB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213128

Device Name
IntraOpVSP software device

Indications for Use *(Describe)*

IntraOpVSP is a software device that is indicated for use with an augmented reality head-mounted display which allows for visualization and orientation of 3D digital models of selected structures of a patient's anatomy.

IntraOpVSP is intended to supplement conventional Virtual Surgical Planning (VSP) by facilitating perception of the shape and scale of a patient's anatomical targets for use in preoperative planning and heads-up 3D visualization during surgery.

IntraOpVSP is not intended to provide diagnosis or to guide surgical instrumentation. It is not to be used for stereotactic procedures or surgical navigation.

IntraOpVSP is intended for use by surgeons who have been trained to operate IntraOpVSP. IntraOpVSP software is designed for use with performance-tested hardware specified in the User Manual.

Type of Use *(Select one or both, as applicable)*

X Prescription Use (Part 21 CFR 801 Subpart D) - Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) SUMMARY

SUBMITTER:	**Submitted on behalf of:**
Company Name:	**Xironetic, LLC**
Address:	712 N. Broadway, Ave. Oklahoma City, OK 73102, USA
Telephone:	**605-412-3574**
by:	**Elaine Duncan, M.S.M.E., RAC** **President, Paladin Medical, Inc.** **PO Box 560** **Stillwater, MN 55082**
Telephone:	**715-549-6035**
Fax:	**715-549-5380**
CONTACT PERSON:	**Elaine Duncan**

DATE PREPARED: **September 15, 2022**

TRADE NAME:	**IntraOpVSP software device**
COMMON NAME:	**Imaging Software;**
CLASSIFICATION #	**Class II**
CLASSIFICATION NAME:	**System, Image Processing, Radiological**
REGULATION & PRO CODE:	**21 CFR 892.2050; LLZ**

DEVICE DESCRIPTION:

IntraOpVSP software displays 3D objects as holograms to inform the user on operative planning. It includes functions for 3D object spatial manipulation and orientation. IntraOpVSP software provides additional information to the surgeon by displaying holograms of the surgical plan, anatomical structures, and guides.

INDICATIONS FOR USE:

IntraOpVSP is a software device that is indicated for use with an augmented reality head-mounted display which allows for visualization and orientation of 3D digital models of selected structures of a patient's anatomy. IntraOpVSP software is intended to supplement conventional Virtual Surgical Planning (VSP) by facilitating perception of the shape and scale of a patient’s anatomical targets for use in preoperative planning and heads-up 3D visualization during surgery.

IntraOpVSP is not intended to provide diagnosis or to guide surgical instrumentation. It is not to be used for stereotactic procedures or surgical navigation. IntraOpVSP is intended for use by surgeons who have been trained to operate IntraOpVSP. IntraOpVSP software is designed for use with performance-tested hardware specified in the User Manual.

SUBSTANTIAL EQUIVALENCE:

The proposed software device, IntraOpVSP, is substantially equivalent to the predicate device, OpenSight (K172418). The intended use of both the proposed device and predicate device is for visualizing 3D patient data using augmented reality for planning purposes; therefore, the devices have the same intended use or general purpose. The two devices have equivalent technological characteristics, with slight differences in software features as described below:

IntraOpVSP software utilizes 3D models that are pre-segmented, typically from CT or MRI data, generated by Virtual Surgical Planning software. OpenSight is intended to enable users to segment previously acquired 3D datasets.

IntraOpVSP's software features are designed for preoperative planning purposes and to evaluate surgical options during surgery. OpenSight's software features are designed for preoperative localization and preoperative planning of surgical options. Neither device is intended for intraoperative use or stereotactic procedures.

When used according to its labeling, IntraOpVSP software raises no questions of safety and effectiveness relative to the predicate device. The table below demonstrates the similarities in technological characteristics and software features between IntraOpVSP and the predicate device, OpenSight. Differences are indicated in the table, but the characteristics or features with differences are deemed equivalent if no questions of safety or effectiveness are raised when the proposed device is used according to its labeling.

Item	Subject Device: IntraOpVSP	Predicate Device: OpenSight (K172418)	Comments
Indications for Use	IntraOpVSP is a software device that is indicated for use with an augmented reality head-mounted display which allows for visualization and orientation of 3D digital models of selected structures of a patient's anatomy. IntraOpVSP is intended to supplement conventional Virtual Surgical Planning (VSP) by facilitating perception of the shape and scale of a patient's anatomical targets for use in preoperative planning and heads-up 3D visualization during surgery. IntraOpVSP is not intended to provide diagnosis or to guide surgical instrumentation. It is not to be used for stereotactic procedures or surgical navigation.	OpenSight is intended to enable users to display, manipulate, and evaluate 2D, 3D, and 4D digital images acquired from CR, DX, CT, MR, and PT sources. It is intended to visualize 3D imaging holograms of the patient, on the patient, for pre- operative localization and preoperative planning of surgical options. OpenSight is designed for use only with performance-tested hardware specified in the user documentation. OpenSight is intended to enable users to segment previously acquired 3D datasets, overlay, and register these 3Dsegmented datasets with the same anatomy of the patient in order to support preoperative analysis.	Equivalent – IntraOpVSP focuses on 3D data from CT, MR and PT sources.

Item	Subject Device: IntraOpVSP	Predicate Device: OpenSight (K172418)	Comments
	IntraOpVSP is intended for use by surgeons who have been trained to operate IntraOpVSP. IntraOpVSP software is designed for use with performance-tested hardware specified in the User Manual.	OpenSight is not intended for intraoperative use. It is not to be used for stereotactic procedures. OpenSight is intended for use by trained healthcare professionals, including surgeons, radiologists, chiropractors, physicians, cardiologists, technologists, and medical educators. The device assists doctors to better understand anatomy and pathology of patient.	
Intended Use Environment	Not for intraoperative use. For use in healthcare settings, such as hospitals, clinics and operating rooms	Not for intraoperative use. For use in healthcare settings, such as hospitals and clinics	Equivalent – IntraOpVSP is also to be used for planning purposes during surgery.
System Components	• Headset with near eye see-through display and tracking camera • Software application • Optical tracking technology	• Headset with near eye see-through display and tracking camera • Software application • Optical tracking technology	Equivalent.
Modes of Operation	• System Set-up • Preoperative scan • Preoperative planning and planning during surgery • VSP Data Import • 3D Data Orientation	• System Set-up • Preoperative scan • Preoperative planning • Scan Import • Patient Registration	Equivalent.
Localization Technology	Mesh surface maps	Mesh surface maps	Equivalent.
User Interface	• Voice commands • Hand gestures • Multiple heads-up menu displays	• Voice commands • Hand gestures • Multiple heads-up menu displays	Equivalent.
Visualization Platform	Augmented reality using near-eye see-through display; data displayed on patient's anatomy for preoperative use and as heads-up display during a surgical procedure	Augmented reality using near-eye see-through display; data displayed on patient's anatomy	Equivalent.
Display Frame Rate	60 fps	60 fps	Equivalent.
Medical Device Interfaces	Pre-operative planning workstation Virtual Surgery Planning server	Pre-operative planning workstation Novarad PACS server	Equivalent – Virtual Surgery Planning server provides 3D data to IntraOpVSP instead of Novarad PACS server.

Item	Subject Device: IntraOpVSP	Predicate Device: OpenSight (K172418)	Comments
Communication between headset and computer/server	Wireless, encrypted	Wireless, encrypted	Equivalent.

SUMMARY of TESTING:

Both design verification and design validation were successfully conducted as part of the testing for the IntraOpVSP software device. Design verification was successful in that the design output specifications satisfactorily met the design input requirements. Similarly, design validation was successfully completed, and testing met all predetermined acceptance criteria. The testing performed was simulated use, and actual use in simulated surgery. No additional risks to the safety or effectiveness of the device were identified from testing. The following standards and guidance documents were referenced in conducting this testing:

- Performance of the augmented reality display was determined suitable for the intended use by characterizing its gamma response, contrast and contrast ratio, resolution, luminance and luminance variation, virtual field of view, display obstructions, and distortion, with testing to IEC 63145-20-10: 2019 and IEC 63145-20-20: 2019 as applicable.
- Validation with intended users: validation of training protocol and validation of trained users' operation of the device in a simulated surgical environment, followed "Guidance for Industry and Food and Drug Administration Staff, February 3, 201" and IEC 62366-1:2015 for Human Factors and Usability testing.
- Hazard analysis was performed following ISO 14971: 2019, and all hazards identified had mitigations implemented and validated through testing, where applicable, to determine acceptable residual risk.
- Software verification and validation was performed according to IEC 62304: 2015: Medical Device Software – Software Lifecycle processes and FDA's guidance on Software as Medical Device (SAMD): Clinical Evaluation – Guidance for Industry and Food and Drug Administration Staff, December 8, 2017.

SAFETY AND EFFECTIVENESS CONCLUSION:

Testing demonstrates that IntraOpVSP is at least as safe and effective as the predicate device. Use of IntraOpVSP during surgery provides additional benefits for surgical planning with equivalent safety when used according to its labeling. Based on the documentation submitted in this premarket application, including performance testing and device labeling, along with the benefit-risk analysis, IntraOpVSP is concluded to be substantially equivalent to the predicate device.