Hoth Intelligence Inc.
% Kelliann Payne
Partner
Hogan Lovells US LLP
1735 Market Street, Suite 2300
PHILADELPHIA, PENNSYLVANIA 19103

September 14, 2023

Re: K232189
Trade/Device Name: OrionXR
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: July 24, 2023
Received: July 24, 2023

Dear Kelliann Payne:

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,

Jessica Lamb

Jessica Lamb,
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: OMB No. 0910-0120
Expiration Date: June 30, 2023
See PRA Statement on last page

510(k) Number *(if known)*
K232189

Device Name

OrionXR

Indications for Use *(Describe)*

OrionXR is a software device for display, manipulation, and evaluation of externally-generated 3D models of patient anatomy through an Augmented Reality Head Mounted Display (HMD) to assist in visualization, planning and communication of treatment options.

OrionXR is indicated for use by qualified healthcare professionals including but not restricted to radiologists, non-radiology specialists, physicians, and technologists.

Digital models viewed through the HMD are for informational purposes only and not intended for diagnostic use. OrionXR is not intended to guide surgical instrumentation and it is not to be used for stereotactic procedures or surgical navigation.

OrionXR software is designed for use with performance-tested hardware specified in the User Manual.

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.

510(k) SUMMARY
Hoth Intelligence, Inc.'s OrionXR
K232189

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared:

Hoth Intelligence Inc.
1700 Market Street Unit 1005,
Philadelphia, PA 19103

Contact Person: Kelliann Payne, Hogan Lovells US LLP
Phone: (267) 675-4600
Date Prepared: September 14, 2023

Name of Device: OrionXR

Common or Usual Name: Medical image management and processing system

Classification and Product Code: 21 CFR 892.2050; LLZ

Predicate Device: Xironetic, LLC's IntraOpVSP Software Device (K213128)

Intended Use / Indications for Use

OrionXR is a software device for display, manipulation, and evaluation of externally-generated 3D models of patient anatomy through an Augmented Reality Head Mounted Display (HMD) to assist in visualization, planning and communication of treatment options.

OrionXR is indicated for use by qualified healthcare professionals including but not restricted to radiologists, non-radiology specialists, physicians, and technologists.

Digital models viewed through the HMD are for informational purposes only and not intended for diagnostic use. OrionXR is not intended to guide surgical instrumentation and it is not to be used for stereotactic procedures or surgical navigation.

OrionXR software is designed for use with performance-tested hardware specified in the User Manual.

Technological Characteristics

OrionXR includes a server for uploading pre-acquired 3D annotations of patient anatomy and the Microsoft Hololens 2 head mounted display for visualizing the models via a Mixed reality platform. The components of the device include:

1. Web Server – Users can load 3D annotations of anatomy to OrionXR web server which can then be accessed on the Head mounted display.

2. Head Mounted Display – OrionXR is compatible with the Microsoft Hololens 2. A user is able to access 3D digital models on the headset. User can manipulate the model in three dimensions of translational and rotational space.

Performance Data

Software verification and validation were successfully conducted and is summarized below.

Design verification and validation was performed to ensure that output specifications meet design input requirements:

- Dimensional Accuracy of 3D Models
- Optical Performance of Headset Display: Contrast ratio, Resolution, Field of View, Luminance Uniformity, Eyebox, Distortion, Frame Rate
- Qualitative Assessment of 3D Anatomic Models.

Human Factors and Usability engineering testing was also performed to identify use errors that could result in serious harm to the patient or user, as well as to develop relevant risk mitigation measures. This testing included simulated use replicative of both the intended use and the intended environment of use. No additional use-related risks to the safety or effectiveness of the device were identified.

Substantial Equivalence

The OrionXR is as safe and effective as the IntraOpVSP (K213128). The OrionXR has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate devices. The minor technological differences between the OrionXR and its predicate device raise no new issues of safety or effectiveness. Performance data demonstrate that the OrionXR is as safe and effective as IntraOpVSP (K213128). Thus, the OrionXR is substantially equivalent.

	Subject Device OrionXR	**Predicate Device IntraOpVSP (K213128)**
Indication of Use	OrionXR is a software device for display, manipulation, and evaluation of externally-generated 3D models of patient anatomy through an Augmented Reality Head Mounted Display (HMD) to assist in visualization, planning and communication of treatment options. OrionXR is indicated for use by qualified healthcare professionals including but not restricted to radiologists, non-radiology specialists, physicians, and technologists. Digital models viewed through the HMD are for informational purposes only and not intended for diagnostic use. OrionXR is not intended to guide surgical instrumentation and it is not to be used for stereotactic procedures or surgical navigation.	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

	OrionXR software is designed for use with performance-tested hardware specified in the User Manual.	trained to operate IntraOpVSP. IntraOpVSP software is designed for use with performance-tested hardware specified in the User Manual.
Intended Use Environment	Not for intraoperative use. The software is intended to be used in the following environments: • Operating rooms • Office environment within hospitals or any other clinical setting • Intensive Care unit, Emergency room, or any other location where medical care is provided	Not for intraoperative use. For use in healthcare settings, such as hospitals, clinics and operating rooms
Intended users	Qualified healthcare professionals including but not restricted to radiologists, non-radiology specialists, physicians, and technologists.	IntraOpVSP is intended for use by surgeons who have been trained to operate IntraOpVSP.
System Components	• Microsoft Hololens 2 Headset with near eye see-through display • OrionXR Software application	• Microsoft Hololens 2 Headset with near eye see-through display • Software application
Display Frame Rate	60 fps	60 fps
Medical Device Interfaces	Pre-operative planning workstation OrionXR server	Pre-operative planning workstation Virtual Surgery Planning server
Communication between Headset and Computer	Wireless—WiFi communication with OrionXR server, encrypted	Wireless, encrypted
HMD Power Source	Lithium Batteries + 18W charger	Lithium Batteries + 18W charger
Biocompatibility	N/A	N/A
Sterilization	Sterilization not required	Sterilization not required
Data Type Supported	• STL • OBJ	• STL • OBJ

Conclusions

OrionXR is substantially equivalent to the predicate device, IntraOpVSP. OrionXR has the same intended use, similar indications for use, technological characteristics and principles of operation as its predicate device. Testing demonstrates that OrionXR is capable of accurately uploading and visualizing 3D anatomic models on a HMD. Thus, OrionXR does not raise different questions of safety and effectiveness and is substantially equivalent to the predicate device.