MediView XR, Inc.
Adam Cargill
Director, QARACA
10000 Cedar Ave
Ste# Gcic 2-153
CLEVELAND, OHIO 44106

July 13, 2023

Re: K223125
Trade/Device Name: Xr90 (xr90-sys)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: June 9, 2023
Received: June 12, 2023

Dear Adam Cargill:

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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K223125

Device Name
XR90 (XR90-SYS)

Indications for Use *(Describe)*
The XR90 (XR90-SYS) is a medical display workstation intended for 3D image visualization and image interaction in conjunction with traditional imaging and monitors. The virtual images are generated from tracked Ultrasound, tracked interventional device, and 3D volumetric data acquired from CT sources and stereoscopically projected such that the proximity of the virtual interventional device is displayed relative to live ultrasound and 3D models from previously acquired CT. The device is intended to provide visual information and reference to be used by the health care professionals for analysis of surgical options during pre-operative planning, and the heads-up, intra-operative display of the images during ultrasound-guided needle-based procedures. Virtual images on the heads-up display should always be used in conjunction with traditional monitors.

The XR90 (XR90-SYS) system is intended to be used as an adjunct to the interpretation of images performed using diagnostic imaging systems and is not intended for primary diagnosis.

The XR90 (XR90-SYS) system is intended to be used as a reference display for consultation and guidance to assist the clinician who is responsible for making all final patient management decisions.

During system use, the position and orientation tracking of the interventional instruments should always be available to the clinician on traditional imaging and monitors.

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.**

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# 510(k) Summary

This summary of safety and effectiveness information is submitted in accordance with 21 CFR §807.92.

**Sponsor:**
MediView XR, Inc.
10000 Cedar Ave
STE GCIC 2-153
Cleveland, OH 44106
Establishment Registration Number: 9102640
Phone: (661) 917-9775

**Contact:**
Adam Cargill
Director, QARACA

**Date Prepared:**
July 12, 2023

**Subject Device:**
Trade Name: XR90 (XR90-SYS)
Submission Number: K223125
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management and Processing System
Regulatory Class: Class II
Product Code: LLZ
Common Name: System, Image Processing, Radiological

**Predicate Device:**
Trade Name: HOLOSCOPE-i
Premarket Notification: K210072
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management and Processing System
Regulatory Class: Class II
Product Code: LLZ
Common Name: System, Image Processing, Radiological

**Reference Device:**
Trade Name: PercuNav Image Fusion and Interventional Navigation
Premarket Notification: K170716
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: JAK
Common Name: System, X-Ray, Tomography, Computed
Associated Product Code: IYO, LLZ
Common Name: System, Imaging, Pulsed Echo, Ultrasonic

**Device Description**

The MediView™ XR90 (XR90-SYS) system is an augmented reality-based medical device to be used adjunctively to clinical ultrasound (US) systems, with the ability to stereoscopically project and fuse standard-of-care US with digital anatomical models based on pre-procedural computed tomography (CT) imaging in biopsies and percutaneous ablations to overcome the limitations of two-dimensional image fusion. The XR90 (XR90-SYS) system provides visual information and remote collaboration features.

XR90 (XR90-SYS) and cleared image fusion devices spatially register and project virtual representations of a) tracked interventional instruments and b) imaged patient anatomy in a common coordinate system. Accordingly, the use of XR90 (XR90-SYS) involves the co-registration of virtual objects (tracked device, US, and CT) for visual information and does not involve use of stereoscopic projection to physical (i.e., real-world) anatomy for navigation, consistent with predicate devices. XR90 (XR90-SYS) spatially registers and stereoscopically co-projects three types of virtual objects: (1) Holographic Light Ray (HLR), (2) CT-based virtual anatomy, and (3) live ultrasound b-sector (Flashlight) with the HUD ultrasound display/augmented reality user interface, while maintaining the same principle of operation compared to predicate devices. Accordingly, the paired registration of holographic entities are:

(1) **HLR** and virtual **US-sector** (Flashlight),
(2) **CT-based** virtual anatomy and virtual **US-sector** (Flashlight), and
(3) **HLR** and **CT-based** virtual anatomy.

The system is comprised of a commercial, off-the-shelf augmented reality head-mounted display, wirelessly connected to a streamer which interfaces with a GE Vivid iq ultrasound system and an electromagnetic (EM) field generator. The US signal is transmitted from the streamer to the head-mounted display, where a virtual display of the US image is stereoscopically projected into the user's field-of-view in conjunction with pre-acquired CT-based images and tracked instrumentation.

The XR90 (XR90-SYS) system is capable of teleprocedural collaboration through the head-mounted display using Microsoft Dynamics 365 Remote Assist, allowing for other healthcare professionals to securely connect remotely to the head-mounted display, viewing the US signal and communicating (both through voice and needle annotation on the screen) in real-time with the local proceduralist. The remote collaborator may interact with the proceduralist via mobile device, laptop, desktop, or head-mounted display but the collaborator participates as an observer and should not make care decisions. The combination of teleprocedure communication and Holographic Needle Guide features provide workflow and ergonomics to the user for pre-operative planning and intra-operative display of virtual images. XR90 (XR90-SYS) is intended to be used adjunctively to standard of care imaging and provides guidance to the user. Proceduralists must refer to standard of care (conventional monitors) and prioritize clinical experience and/or judgement when using the XR90 (XR90-SYS) system.

**Intended Use**

The XR90 (XR90-SYS) is a medical display workstation intended for 3D image visualization and image interaction in conjunction with traditional imaging and monitors. The virtual images are generated from tracked Ultrasound, tracked interventional device, and 3D volumetric data acquired from CT sources and stereoscopically projected such that the proximity of the virtual interventional device is displayed relative to live ultrasound and 3D models from previously acquired CT. The device is intended to provide visual information and reference to be used by the health care professionals for analysis of surgical options during pre-operative planning, and the heads-up, intra-operative display of the images during ultrasound-guided needle-based procedures. Virtual images on the heads-up display should always be used in conjunction with traditional monitors.

The XR90 (XR90-SYS) system is intended to be used as an adjunct to the interpretation of images performed using diagnostic imaging systems and is not intended for primary diagnosis.

The XR90 (XR90-SYS) system is intended to be used as a reference display for consultation and guidance to assist the clinician who is responsible for making all final patient management decisions.

During system use, the position and orientation tracking of the interventional instruments should always be available to the clinician on traditional imaging and monitors.

The intended use and indications for use are similar to the predicate Real View Imaging Ltd. HOLOSCOPE-i (K210072, referred to as HOLOSCOPE-i throughout this document).

**Summary of Technological Characteristics**

The XR90 (XR90-SYS) system has a similar intended use and indications for use, principles of operation, and technological characteristics as the legally marketed predicate device, HOLOSCOPE-i (K210072) and the legally marketed reference device, PercuNav Image Fusion and Navigation System (K170716).

- **Intended Use:** Like HOLOSCOPE-i, the proposed XR90 (XR90-SYS) is a medical display workstation intended for 3D image visualization and image interaction. Additionally, both devices are intended to be used as a reference display as an adjunct to the interpretation of images performed using legally marketed diagnostic imaging systems and are not intended for primary diagnosis.
- **Intended Users:** Like HOLOSCOPE-i, the proposed XR90 (XR90-SYS) is intended to be used by health care professionals who are responsible for making all final patient decisions.
- **Principles of Operation:** Like HOLOSCOPE-i, the proposed XR90 (XR90-SYS) receives medical imaging data from standard imaging modalities and generates 3D models to enable the health care professional to visualize the patient's anatomy. Like PercuNav, the proposed XR90 (XR90-SYS) provides image-guided diagnostic and intervention that enables fusion of diagnostic images and pre-procedural reference of tracked instruments to physician-defined targets.
- **Visualization and Navigation:** Like the HOLOSCOPE-i, the proposed XR90 (XR90-SYS) provides three-dimensional visualization and image interaction by acquiring data from CT and ultrasound sources to intraoperatively display the images to provide visual information to be used by the health care professional. Similar to the reference device, the proposed XR90 (XR90-SYS) provides real-time, three-dimensional visualization and reference tools for all stages of intervention, including pre-procedure planning and intra-procedural virtual display of images. The system uses transformed two-dimensional patient images into representations that can be fused with live ultrasound.
- **Tool Tracking:** Both the reference device and XR90 (XR90-SYS) utilize EM tracking to track an ultrasound probe and interventional instrument (eTRAX - K092619). Similar hardware is utilized for the EM field generator, cable connection interface, tracked interventional instrument, and micro-EM sensors.
- **Registration:** Similar to the reference device, the proposed XR90 (XR90-SYS) performs spatial mapping from one image space to another image space (registration), allowing the physician to correlate scan sets with each other and to the tracked instrument.
    - **Automatic Registration:** The reference device, PercuNav, contains an automatic registration method, in which the ultrasound probe is swept across anatomical landmarks, and then the ultrasound image is registered with the CT images. Similarly, XR90 (XR90-SYS) contains an automatic registration feature in which a user gazes at each Registration Marker in a sweeping motion, and the system automatically performs the registration of CT-based Holographic Anatomy, ultrasound Flashlight, and tracked interventional instrument using the registration method described in the Device Description and Principles of Operation document.

  - **Manual Registration:** The reference device, PercuNav, contains a manual registration method in which corresponding points on different imaging modalities are used to translate the images. Similarly, XR90 (XR90-SYS) contains an "Adjustment" feature, in which corresponding points on the CT-based Holographic Anatomy and ultrasound Flashlight are used to translate the CT-based Holographic Anatomy to the real-time ultrasound.
- **Projected Path of Interventional Instrument:** The reference device contains a "biopsy" line that is aligned with the user-specified target prior to insertion. This is similar to the Holographic Needle Guide and alignment of the Holographic Light Ray with the user-specified target on the Flashlight to be used for pre-operative planning.
- **Targeting Feedback Indicators**: The reference device contains an "Ultrasound Guidance Bar" on the right side of the screen that helps detect whether the target is in the ultrasound scanning plane after a target is set. Similarly, the XR90 (XR90-SYS) system contains visual and auditory feedback indicators on in-plane or out-of-plane targeting while aligning the Holographic Light Ray with the Ultrasound Flashlight.

Based on the above comparison, the XR90 (XR90-SYS) has a similar intended use and similar technological and functional features as the predicate device in providing tools and workflows designed to support users with 3D visualization and image interaction with medical device images. Similar to the cited predicate device, XR90 (XR90-SYS) is used for image viewing and interaction both prior to and during procedures.

The XR90 (XR90-SYS) system is substantially equivalent to the predicate device with regards to intended use and technological characteristics and any differences between the XR90 (XR90-SYS) system and the predicate do not introduce new questions of safety or efficacy. Performance testing demonstrates the device performs as intended.

**Summary of Performance Data**

Verification and validation testing data summarized below were provided in support of the substantial equivalence documentation.

<u>Non-Clinical Performance Testing:</u>

Non-clinical bench testing on the XR90 (XR90-SYS) system was performed to demonstrate the system meets the performance specifications per the device's intended use. The testing concluded that XR90 (XR90-SYS) does not raise any new questions of safety and effectiveness. This included the System Accuracy Verification, Cadaver Study which concluded that the registration and fusion of virtual images was within acceptable limits in a phantom and cadaver model. Additionally, the system performance was evaluated in an animal model. System accuracy performance testing is summarized below:

| Test | Mean TRE (mm) | 95% Upper Bound for TRE (mm) | TRE Measured at Mean Needle Depth of (cm): |
|---|---|---|---|
| Phantom | 2.543 mm | 2.726 mm | 7.1 cm |
| Cadaver | 2.293 mm | 2.825 mm | 8.5 cm |
| Animal | 2.9 mm | 3.4 mm | 7.6 cm |

The angular errors, including in-plane and out-of-plane error between the tip of the needle and target was measured in an animal model, and is summarized below:

| Test | Mean Angular Error (degrees) | 95% Upper Bound (degrees) |
|---|---|---|
| In-plane angular errors | 7.08º | 8.77º |
| Out-of-plane angular errors | 4.79º | 6.50º |

The following non-clinical testing was conducted to evaluate the device:

- Bench testing performance tests demonstrated the system meets its performance requirements by verifying the following elements:
  - Measurement of Positional Accuracy of the EM Tracking Subsystem in accordance with ASTM F2554-22
  - Accuracy of the system registration, including Target Registration Error and Image Fusion Registration Error, in a benchtop phantom study and in a cadaver model, as well as measurement validation of distances measured in the system against a ground truth.
  - Latency and data communication on the benchtop
  - Registration/image target tracking on the benchtop
- Electrical safety was tested in accordance with ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
- Electromagnetic Compatibility (EMC) was tested in accordance with IEC 60601-1- 2:2014 - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.
- System cleaning and disinfection validation was performed according to AAMI TIR 30:2011/(R)2016, AAMI TIR 12:2010, and FDA guidance:" Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff" (March 17, 2015).
- Sterilization validation according to ISO 11135:2014
- The biocompatibility of all user contact materials was tested according to ISO 10993-1:2018 and FDA guidance on the use of ISO 10993-1.
- Software verification and validation testing was conducted as required by IEC 62304 and FDA guidance on general principles of software validation, January 11, 2002.

- Usability evaluation - the system was validated with intended users in simulated use conditions to ensure tasks, including critical tasks, were met and no new issues of safety or effectiveness were raised.

The following performance testing was also conducted to evaluate the device:

- The XR90 (XR90-SYS) system was verified and validated in a GLP porcine study that evaluated the safety, efficacy, and accuracy (including Target Registration Error and angular errors) of the system when used in adjunct to standard-of-care imaging during ultrasound-guided needle-based procedures in porcine models. Secondary endpoints of the study included evaluating overall procedure time, complications, and overall clinical usability.

**Substantial Equivalence Conclusion**

MediView XR maintains that the subject device is substantially equivalent to the legally marketed predicate based on the comparison information provided above and further extrapolated in the substantial equivalence comparison table below. Verification testing, including system level tests, performance tests, and safety tests established the performance, functionality, and reliability characteristics of the system. It is concluded that the XR90 (XR90-SYS) system is substantially equivalent to the legally marketed predicate device (K210072).

# Substantial Equivalence Table

The table below outlines the similarities and differences between the subject XR90 (XR90-SYS) system and the predicate Real View Imaging Ltd. HOLOSCOPE-i system, in addition to the Philips PercuNav Image Fusion and Interventional Navigation system as a reference device.

| | **Subject Device: MediView XR90 (XR90-SYS) System (K223125)** | **Predicate Device: Real View Imaging Ltd. HOLOSCOPE-i (K210072)** | **Reference Device: Philips PercuNav Image Fusion and Interventional Navigation System (K170716)** | **Explanation of Differences** |
|---|---|---|---|---|
| **Submission Number** | K223125 | K210072 | K170716 | N/A |
| **Product Code(s)** | LLZ | LLZ | JAK/IYO/LLZ | Equivalent to predicate device. |
| **Regulation** | Medical Image Management and Processing System (21 CFR 892.2050) | Medical Image Management and Processing System (21 CFR 892.2050) | Computed Tomography X-Ray System (21 CFR 892.1750) | |
| **Intended Use** | The XR90 (XR90-SYS) is a medical display workstation intended for 3D image visualization and image interaction in conjunction with traditional imaging and monitors. The virtual images are generated from tracked Ultrasound, tracked interventional device, and 3D volumetric data acquired from CT sources and stereoscopically projected such that the proximity of the virtual interventional device is displayed relative to live ultrasound and 3D models from previously acquired CT. The device is intended to provide visual information and reference to be used by the health care | The HOLOSCOPE-i is a medical display workstation intended for 3D image visualization and image interaction. The holograms are generated from 3D volumetric data acquired from CT and Ultrasound sources. The device is intended to provide visual information to be used by the health care professional for analysis of surgical options, and the intraoperative display of the images. The HOLOSCOPE-i is intended to be used as an adjunct to the interpretation of images performed using diagnostic imaging systems and is not intended for primary diagnosis. The HOLOSCOPE-i is intended | The PercuNav system is a stereotaxic accessory for computed tomography (CT), magnetic resonance (MR), ultrasound (US), and positron emission tomography (PET). CT, Ultrasound, PET, and MR may be fused in various combinations, such as CT with MR, MR with ultrasound, and so on. It may include instrumentation to display the simulated image of a tracked insertion tool such as a biopsy needle or probe on a computer monitor screen that shows images of the target organs and the current and the projected future path of the interventional | There are no fundamental differences in the intended use of the XR90 (XR90-SYS) system compared to the predicate device.<br>• The XR90 (XR90-SYS) system is not an accessory to imaging modalities, but rather, indicated to be used adjunctively to ultrasound. Ultrasound images may be fused with previously acquired CT imaging, whereas the reference allows for fusion in various combinations. |

| | **Subject Device: MediView XR90 (XR90-SYS) System (K223125)** | **Predicate Device: Real View Imaging Ltd. HOLOSCOPE-i (K210072)** | **Reference Device: Philips PercuNav Image Fusion and Interventional Navigation System (K170716)** | **Explanation of Differences** |
|---|---|---|---|---|
| | professionals for analysis of surgical options during pre-operative planning, and the heads-up intra-operative display of the images during ultrasound-guided needle-based procedures. Virtual images on the heads-up display should always be used in conjunction with traditional monitors.<br><br>The XR90 (XR90-SYS) system is intended to be used as an adjunct to the interpretation of images performed using diagnostic imaging systems and is not intended for primary diagnosis.<br><br>The XR90 (XR90-SYS) system is intended to be used as a reference display for consultation and guidance to assist the clinician who is responsible for making all final patient management decisions.<br><br>During system use, the position and orientation tracking of the interventional instruments should always be available to the clinician on traditional imaging and monitors. | to be used as a reference display for consultation to assist the clinician who is responsible for making all final patient management decisions. | instrument. The PercuNav system is intended for treatment planning and guidance for clinical, interventional, or diagnostic procedures.<br><br>The PercuNav system also supports an image-free mode in which the proximity of the interventional device is displayed relative to another device. The PercuNav system is intended to be used in interventional and diagnostic procedures in a clinical setting.<br><br>The PercuNav system is also intended for use in clinical interventions to determine the proximity of one device relative to another.<br><br>Example procedures include, but are not limited to, the following:<br>• Image fusion for diagnostic clinical examinations and procedures<br>• Soft tissue biopsies (liver, lung, kidney, breast, pancreas, bladder, adrenal glands, lymph node, mesentery, and so on.)<br>• Soft tissue ablation (liver, kidney, breast, pancreas, lung, and so on)<br>• Bone ablations<br>• Bone biopsies | • The XR90 (XR90-SYS) system utilizes a head-mounted display for viewing imaging in augmented reality (AR), as opposed to the predicate, which uses an optical unit attached to a boom.<br><br>• XR90 (XR90-SYS) is a supplement to live imaging in clinical interventions and is not meant to replace standard of care imaging.<br><br>• Similar to the reference, XR90 (XR90-SYS) is not intended to be the sole guidance for any procedure. Philips also included this statement in a more recent 510(k) submission for their PercuNav device (K201053), so this is similar in both devices.<br><br>The differences in intended use between the predicate and XR90 (XR90-SYS) do not affect the safety or efficacy of the device, as each have similar underlying technology and basic components. |

| | Subject Device: MediView XR90 (XR90-SYS) System (K223125) | Predicate Device: Real View Imaging Ltd. HOLOSCOPE-i (K210072) | Reference Device: Philips PercuNav Image Fusion and Interventional Navigation System (K170716) | Explanation of Differences |
|---|---|---|---|---|
| | | | • Nerve blocks and pain management<br>• Drainage placements<br>• Tumor resections | |
| **Intended Use Environment** | Hospital operating rooms and procedure rooms | Interventional suites, hybrid operating rooms, and diagnostic clinics | Hospital operating rooms, outpatient surgery centers and procedure rooms | Similar to the predicate. XR90 (XR90-SYS) is not intended to be used in diagnostic clinics, as the EM field generator is designed to be compatible with tables found in operating or procedure rooms. |
| **Main System Components** | • EM Field Generator<br>• Tool Connection Unit (SCU/SIU)<br>• Computing Hardware (Server/Router)<br>• Microsoft HoloLens 2 head-mounted display configured with XR90 (XR90-SYS) Software<br>• Instrumentation [see 'Tracking' below] | • Optical Unit<br>• Computing Hardware<br>• Cart and boom mechanical fixture to mechanically connect the Optical Unit and system computer<br>• 3D Control Device | • EM Field Generator<br>• Tool Connection Unit (TCU)<br>• Computing Hardware<br>• Monitor to display PercuNav Software<br>• Instrumentation [see 'Tracking' below] | XR90 (XR90-SYS) uses a Microsoft HoloLens 2 to display imaging and tracked instrumentation for pre-operative planning and intra-operative display of virtual images, as opposed to the predicate device, which utilizes an optical unit connected to a boom mechanical fixture.<br><br>Predicate device uses a 3D Control Device for interaction, while XR90 (XR90-SYS) is "hands-free," using voice and hand gestures. |

| | **Subject Device: MediView XR90 (XR90-SYS) System (K223125)** | **Predicate Device: Real View Imaging Ltd. HOLOSCOPE-i (K210072)** | **Reference Device: Philips PercuNav Image Fusion and Interventional Navigation System (K170716)** | **Explanation of Differences** |
|---|---|---|---|---|
| **Modes of Operation** | • On a head-mounted display, the interaction with the software is performed using hand gestures. Voice commands are optional for further interaction with the software.<br><br>• Ultrasound parameters may be changed on the local US system, not in the XR90 (XR90-SYS) software.<br><br>There are different viewing options for the US imaging, including:<br>• Heads-Up Display (HUD)<br>• Registered Holograms (In-situ Flashlight Mode registered with CT-based models and tracked instrumentation) | • 3D Control Device is used for interfacing with the hologram.<br><br>• 3D volumetric data is received from CT or US and generates a hologram in the holographic display.<br><br>• Spatial Light Modulator (SLM) is used to generate holograms and guided to the desired projection area via the optical system adjacent to the SLM. | • The viewing of imaging and tracked instrumentation is displayed on a computer monitor screen.<br><br>• CT, Ultrasound, PET, and MR may be fused in various combinations, such as CT with MR, MR with ultrasound, and so on. | The principles of operation between the subject and predicate device are similar at the core: A proceduralist is viewing fused imaging on a computer screen, whether via a traditional monitor or head-mounted display. Each system has different modes of viewing information.<br><br>XR90 (XR90-SYS) uses hand gestures and voice commands for interaction rather than interaction with a 3D control device. |
| **Patient Contacting Components** | Registration Markers | None | Patient Tracker | Equivalent to reference device. Both use skin-contacting components that are EM-sensor equipped. |
| **Tracking** | EM Tracking<br>• Registration Markers<br>• Ultrasound Tracker<br>• Tracked Interventional Instrument (Biopsy and RFA Introducers, including eTrax, which has been cleared and | | EM Tracking<br>• Patient Tracker<br>• Ultrasound Tracker<br>• Coaxial Needle Tracker (CNT)<br>• Adaptive Needle Tracker (ANT)<br>• Button Probes | Both the reference and proposed systems have sensor-equipped instrumentation to track the ultrasound and interventional instrument within the tracking environment. |

| | Subject Device: MediView XR90 (XR90-SYS) System (K223125) | Predicate Device: Real View Imaging Ltd. HOLOSCOPE-i (K210072) | Reference Device: Philips PercuNav Image Fusion and Interventional Navigation System (K170716) | Explanation of Differences |
|---|---|---|---|---|
| | marketed by CIVCO Medical [K092619])<br><br>Registration Markers contain an optical image for registration only. | | • Biopsy and RFA Introducers (including eTrax, which has been cleared and marketed by CIVCO Medical [K092619]) | The Registration Markers do not track the patient in real-time—they are intended to assist in the registration of CT-based images with ultrasound and tracked interventional instrument. The PercuNav Patient Tracker tracks the patient movement. |
| **Imaging Modality** | Ultrasound, historical segmented CT images | CT and Ultrasound sources | Ultrasound, CT, MR, PET | None. |
| **Registration Method** | • Automatic Registration<br>• Manual registration | | • Automatic Registration<br>• Manual Registration | Equivalent to reference device. |
| **Medical Device Interfaces** | • GE Vivid iq Premium Edition Ultrasound system<br>• Compatible ultrasound probes<br>• CIVCO eTRAX [K092619]<br>• GE Omega V Angio table | • Compatible 3D ultrasound system | • Compatible ultrasound system<br>• Compatible ultrasound probes<br>• CIVCO eTRAX [K092619] | The XR90 (XR90-SYS) system and the predicate both interface with a compatible ultrasound system via direct connection. The XR90 (XR90-SYS) system has similar medical device interfaces to the reference device. The EM Field Generator is attached to compatible procedure tables using custom table brackets, whereas the EM Field Generator for PercuNav is mounted on an arm that is placed above the patient. |
| **Display Features** | • 3D models of segmented images | • Two optical channels, consisting of a Spatial Light Modulator, an | • 3D view of segmented images | Core technology is equivalent to the predicate device, in |

| | **Subject Device: MediView XR90 (XR90-SYS) System (K223125)** | **Predicate Device: Real View Imaging Ltd. HOLOSCOPE-i (K210072)** | **Reference Device: Philips PercuNav Image Fusion and Interventional Navigation System (K170716)** | **Explanation of Differences** |
|---|---|---|---|---|
| | • 2D images: Ultrasound (Flashlight and Heads-up Display)<br>• Trajectories (Holographic Light Ray)<br>• Trajectory Guidance (Holographic Needle Guide)<br>• Virtual instrument's tip view (Light Ray)<br>• 3D transparent (semi-translucence of 3D models)<br>• 3D Off (only 2D)<br>• 3D follow instrument movement (Light Ray) | RGB coherent light source, a set of lenses and mirrors to direct light to the see-through eyepieces. | • 2D images: Ultrasound, CT (axial, sagittal, coronal), PET, and MR<br>• Trajectories (projected future path of interventional instrument)<br>• Trajectory Guidance | which virtual images are overlaid within the user's physical environment. The subject device uses stereoscopic projection via see-through diffractive planar waveguides, while the predicate uses interference-based Spatial Light Modulators.<br><br>Reference device and subject device are equivalent. Reference device supports PET and PER/CT, as well as fusion of two-dimensional patient images with previously acquired images. XR90 (XR90-SYS) only supports fusion of live ultrasound with previously acquired CT. XR90 (XR90-SYS) does not support or claim diagnostic review of images. |
| **Software Interface (GUI)** | • Visualization control (show/hide virtual anatomy & Flashlight mode)<br>• Patient Selection/Data Import<br>• Buttons for registration<br>• Adjust fusion via Adjustment method (point-to-point method)<br>• Software controls for images<br>• Target selection and planned trajectory management | • Interactions with system<br>• Selection of tools<br>• Drive workflow<br><br>This includes the ability to:<br>• Visualize<br>• Rotate<br>• Slice<br>• Mark<br>• Measure<br>images displayed holographically. | • Patient selection/data import<br>• Select registration method<br>• Buttons for registration<br>• Adjust fusion (including point-to-point method)<br>• Save registration button<br>• Software controls for images<br>• Target selection<br>• Feedback on target/ultrasound alignment (Ultrasound Guidance Bar) | Software interface is similar to the predicate and reference device. XR90 (XR90-SYS) enables a user to visualize imaging and customize their display via voice and hand gestures, similar to the predicate. Users can mark locations in the CT-based Holographic Anatomy and ultrasound HUD/Flashlight to |

| | Subject Device: MediView XR90 (XR90-SYS) System (K223125) | Predicate Device: Real View Imaging Ltd. HOLOSCOPE-i (K210072) | Reference Device: Philips PercuNav Image Fusion and Interventional Navigation System (K170716) | Explanation of Differences |
|---|---|---|---|---|
| | • Feedback on target/ultrasound alignment (Light Ray auditory and visual indicators) | | • Color / MFI / CEUS | perform a CT adjustment. XR90 (XR90-SYS) registers images with one another, whereas the predicate does not perform registration. Therefore, image rotation is not a capability of XR90 (XR90-SYS). |
| **Communication Between Imaging and Computing Hardware** | • DICOM images imported for segmentation through hospital-approved USB, CD, or DVD.<br>• Real-time ultrasound connected via Ethernet cable to router. | • PACS, USB, or direct from connected compatible 3D ultrasound acquisition modality. | • CT, MR, PET images imported using USB, CD, DVD, or PACS.<br>• Real-time US connected to PercuNav. | Similar. XR90 (XR90-SYS) does not integrate with a PACS system due to the segmentation process that DICOM images must undergo prior to a procedure with the device. |
| **Communication Between Headset and Computing Hardware** | Wireless<br><br>Streaming hardware (MediView Streamer and MediView Router) transmits US imaging from the scanner to the headset over LAN | Embedded PC supporting system | No Headset | Subject device uses a local area network (LAN) to transmit streamed US data to headset, whereas the predicate device has a PC supporting system embedded into the system, which connects to the optical unit.<br><br>Reference device uses a computer monitor screen rather than a head-mounted display for imaging. |

| | Subject Device: MediView XR90 (XR90-SYS) System (K223125) | Predicate Device: Real View Imaging Ltd. HOLOSCOPE-i (K210072) | Reference Device: Philips PercuNav Image Fusion and Interventional Navigation System (K170716) | Explanation of Differences |
|---|---|---|---|---|
| **Display and Optics Technology** | Stereoscopic Holographic Display using near eye see-through holographic lenses/waveguides (Microsoft HoloLens 2) | Stereoscopic Holographic Display using a near eye see-through display (Custom Optical Unit) | Data displayed on a monitor | Equivalent.<br>Reference device uses a computer monitor screen rather than a head-mounted display for imaging. The HoloLens 2 head-mounted display is like a computer monitor, as it is a see-through computer display that runs on Windows 10 Holographic Operating System. |
| **DICOM Compatible** | Yes | Yes | Yes | None |
| **Original 2D/3D image remains visible (acquisition data source)** | Yes (ultrasound) | Yes | Yes | None |