February 23, 2026

SKIA Inc.
% Dave Yungvirt
Third Party Review Group, LLC
7 Giralda Farms, Suite 120a
Madison, NJ 07940
USA

Re: K253486
Trade/Device Name: SKIA-Head (Model: SKIA-ST00)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: February 9, 2026
Received: October 17, 2025

Dear Dave Yungvirt:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K253486

Device Name
SKIA-Head (Model: SKIA-ST00)

Indications for Use *(Describe)*
The SKIA-Head (SKIA-ST00) is a medical display system intended for 3D image visualization and image interaction in conjunction with traditional imaging and monitors. The virtual images are generated from 3D volumetric data previously acquired from CT sources and visualized to 3D patient images being displayed on a tablet PC using 3D cameras.
The device is intended to provide visual information and reference to be used by health care professionals for analysis of surgical options during pre-operative planning.
The device may also be used in a limited, early intraoperative context, specifically during phases in which the patient's skin surface remains consistent with the CT-acquired skin surface model. This generally corresponds to the period after anesthesia but before any manipulation that would deform or alter the patient's external skin surface. This represents a pre-operative to early intraoperative transition phase, during which the patient's posture is fixed and the skin surface remains sufficiently stable for skin-based registration.
The system is intended for visualization and reference purposes only and is not intended for real-time surgical navigation, instrument tracking, or stereotactic guidance.
This device is intended for prescription use only (Rx Only).

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 – Traditional 510(k) K253486

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92.

Submitter Information

Submitter Name:	SKIA Inc.
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Contact Person:	Edward Park, official correspondent of SKIA Inc.
Date of submission:	23 February 2026

Device Information

Proprietary Name(s):	SKIA-Head
Model Name:	SKIA-ST00
Common Name:	System, Image Processing, Radiological
Regulation Name:	Medical Image Management and Processing System
Product Code:	LLZ
Regulation Number:	21 CFR 892.2050
Classification Panel:	Radiology
Device Class:	II

Device Description

The SKIA-Head is an augmented reality-based standalone software device. The device reconstructs digital anatomical 3D models based on pre-procedural computed tomography (CT) images for users to review and fuses it with a real-time patient video image displayed on a tablet PC to generate augmented reality. The system is comprised of SKIA_Processor, SKIA_Application, and SKIA-Server. Users need compatible off-the-shelf hardware such as hospital server to operate SKIA-Server, user's PC to operate SKIA_Processor, 3D camera device to scan a patient and shoot a real time patient video, and iPad to proceed registration and display the AR output image.

The SKIA-Head provides users with review functions such as image position movement, zoom in/out, image reset, image rotation, and segmentation of the CT images. The AR anatomical model fused with the real time patient video can help users accurately recognize the actual location and size of lesions in the patient.

The SKIA-Head projects virtual representations of a) a spatially scanned patient image map using a 3D camera and b) reconstructed CT-based 3D anatomical model. Accordingly, the use of SKIA-Head involves the co-registration of these two virtual objects and real time patient video image displayed on a tablet PC for visual information using projection to real patients.

Indications for Use

The SKIA-Head (SKIA-ST00) is a medical display system intended for 3D image visualization and image interaction in conjunction with traditional imaging and monitors. The virtual images are generated from 3D volumetric data previously acquired from CT sources and visualized to 3D patient images being displayed on a tablet PC using 3D cameras.

The device is intended to provide visual information and reference to be used by health care professionals for analysis of surgical options during pre-operative planning.

The device may also be used in a limited, early intraoperative context, specifically during phases in which the patient's skin surface remains consistent with the CT-acquired skin surface model. This generally corresponds to the period after anesthesia but before any manipulation that would deform or alter the patient's external skin surface. This represents a pre-operative to early intraoperative transition phase, during which the patient's posture is fixed and the skin surface remains sufficiently stable for skin-based registration.

The system is intended for visualization and reference purposes only and is not intended for real-time surgical navigation, instrument tracking, or stereotactic guidance.

This device is intended for prescription use only (Rx Only).

Primary Predicate Device

- XR90 (Model: XR90-SYS, MediView XR, Inc. K223125, 07/13/2023)

  - Common Name: System, Image Processing, Radiological
  - Regulation Name: Medical Image Management and Processing System
  - Device Class: II
  - Product Code: LLZ
  - Regulation Number: 21 CFR 892.2050
  - Classification Panel: Radiology

Secondary Predicate Device

- Ikshana (ImmersiveAR, ImmersiveTouch K230249, 10/16/2023)

  - Common Name: System, Image Processing, Radiological
  - Regulation Name: Medical Image Management and Processing System
  - Device Class: II
  - Product Code: LLZ
  - Regulation Number: 21 CFR 892.2050
  - Classification Panel: Radiology

The SKIA-Head system has a similar intended use and indications for use, principles of operation, and technological characteristics as the legally marketed predicate device, XR90 (K223125).

a. Intended Use and Indications for Use
XR90 employs CT-based modeling and registration to support both surgical planning and intra-operative reference. While the SKIA-Head's intended use is especially focused on preoperative planning in craniomaxillofacial surgery, and the XR90 is specifically indicated for ultrasound-guided needle procedures and includes instrument tracking, these differences do not introduce new questions of safety or effectiveness since the scope of equivalence for the SKIA-Head is limited to the intended use for pre-operative planning and early phase of the general intra-operative display based on previously acquired CT data, and the fundamental purpose of providing an adjunctive visual reference based on CT data remains the same.

b. Intended Users
All the above devices are intended to be used by healthcare professionals who are responsible for making all final patient decisions.

c. Principles of Operation
Like XR90, the proposed SKIA-Head receives medical imaging data from standard imaging modalities and generates 3D models to enable the healthcare professional to visualize the patient's anatomy. The proposed device and the predicate devices provide image-guided review function with CT-based images for surgery and enables the segmentation of the 2D CT images and the registration of 3D models for pre-procedural reference to physician-defined targets.

d. Visualization

Like the Ikshana, the second predicate device, the proposed device provides three-dimensional visualization and image interaction by acquiring data from CT and 3D camera sources to pre- and intra-operatively display the 3D images to provide visual information to be used by the health care professional. This functionality, including the use of a 3D model and patient skin image for surgical planning and display, is identical to the Ikshana, the second predicate device.

e. Registration

Similar to the predicate devices, the proposed SKIA-Head performs spatial mapping from one image space to another image space (registration), allowing the physician to correlate scan sets with each other.

The SKIA-Head features markerless registration, which is also a feature of the second predicate device.

Summary of Technological Characteristics

	Proposed Device	Primary Predicate	Secondary Predicate	Remark
Device Name	**SKIA-Head (model: SKIA-ST00)**	**XR90 (Model: XR90-SYS)**	**Ikshana (ImmersiveAR)**	
510k number		**K223125**	**K230249**	
Manufacturer	**SKIA Inc.**	**MediView XR, Inc.**	**ImmersiveTouch**	
Product Code	LLZ	LLZ	LLZ	
Indications for Use	The SKIA-Head (SKIA-ST00) is a medical display system intended for 3D image visualization and image interaction in conjunction with traditional imaging and monitors. The virtual images are generated from 3D volumetric data previously acquired from CT sources and visualized to 3D patient images being displayed on a tablet PC using 3D cameras. The device is intended to provide visual information and reference to be used by health care professionals for analysis of surgical options during pre-operative planning. The device may also be used in a limited, early intraoperative context, specifically during phases in which the patient's skin surface remains consistent with the CT-acquired skin surface model. This generally corresponds to the period after anesthesia but before any manipulation that would deform or alter the patient's external skin surface. This represents a pre-operative to early intraoperative transition phase, during which the patient's posture is fixed and the skin surface remains sufficiently stable for skin-based registration. The system is intended for visualization and reference purposes only and is not intended for real-time surgical	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	Ikshana is a software device to display medical images. It includes functions for image review, image manipulation, measurements, and 3D visualization. Medical images may only be interpreted using an FDA-cleared display monitor that meets technical specifications that are reviewed and accepted by the FDA. Ikshana 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. Display monitors used for reading medical images for diagnostic purposes must be FDA-approved radiology monitors. Ikshana software is indicated for use by qualified healthcare professionals, including, but not restricted to, radiologists, non-radiology specialists, physicians, and technologists. When accessing the Ikshana software from a wireless stereoscopic head-mounted display (HMD) or mobile device, the images viewed are for informational purposes only and are not intended for diagnostic use.	The indications for use of the primary predicate device and secondary predicate device incorporate the subject device's.

	Proposed Device	Primary Predicate	Secondary Predicate	Remark
Device Name	**SKIA-Head (model: SKIA-ST00)**	**XR90 (Model: XR90-SYS)**	**Ikshana (ImmersiveAR)**	
510k number		**K223125**	**K230249**	
Manufacturer	**SKIA Inc.**	**MediView XR, Inc.**	**ImmersiveTouch**	
	navigation, instrument tracking, or stereotactic guidance. This device is intended for prescription use only (Rx Only).	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.		
Intended Use Environment	Hospital operating rooms and procedure rooms	Hospital operating rooms and procedure rooms	Hospital operating rooms and procedure rooms	Identical
Main System Components	**Software Component** • SKIA_Processor • SKIA_Application • SKIA-Server software **Hardware Component** • 3D camera • iPad	**Software Component** • XR90-SYS **Hardware Component** • EM Field Generator • Tool Connection Unit (SCU/SIU) • Microsoft HoloLens 2 • Tracking sensor	**Software Component** • Ikshana system **Hardware Component** • Microsoft HoloLens 2	Similar (SW+HW) but different type of the hardware components
Modes of Operation	• Pre-operative Surgical Planning Mode – DICOM data review and processing, Segmentation of anatomy, 3D modeling, Virtual planning • Intra-operative Guidance Mode (Augmented Reality) – Markerless registration, AR display, Real-time tracking	• Pre-operative Surgical Planning Mode – DICOM data review and processing, Segmentation of anatomy, 3D modeling, Virtual planning • Intra-operative Guidance Mode (Augmented Reality) – Marker-based registration with sensor fusion, AR display, Ultrasound fusion, Real-time instrument tracking (Navitgation) • Telecollaboration Mode • Education & Training Mode	• Pre-operative Surgical Planning Mode – DICOM data review and processing, Segmentation of anatomy, 3D modeling, Performing virtual surgery, Collaboration with multiple users • Intra-operative Guidance Mode (Augmented Reality) – Markerless registration, Heads-up display, Real-time tracking, Hand and gesture control • Educational and Training Mode	
Patient Contacting Components	N/A	Registration Markers	N/A	Similar to Ikshana (K230249)
Registration & AR Tracking	**Registration & Tracking Method** : Markerless, Computer vision	**Registration & Tracking Method** : Marker-based, Sensor fusion	**Registration & Tracking Method** : Markerless, Computer vision	Similar to Ikshana (K230249)

	Proposed Device	Primary Predicate	Secondary Predicate	Remark
Device Name	**SKIA-Head (model: SKIA-ST00)**	**XR90 (Model: XR90-SYS)**	**Ikshana (ImmersiveAR)**	
510k number		**K223125**	**K230249**	
Manufacturer	**SKIA Inc.**	**MediView XR, Inc.**	**ImmersiveTouch**	
	Key Technology : Depth camera, Skin registration	: Ultrasound-based fusion (fuses pre-op CT with live ultrasound) **Key Technology** : Electromagnetic (EM) Tracking, HMD camera, Optical Markers, Ultrasound	**Key Technology** : HMD camera, Skin registration	
Modality of input image source	CT (DICOM)	CT(DICOM), Ultrasound	CT (DICOM), MRI	Identical to Ikshana (K230249)
Registration Method	Automatic Registration	• Automatic Registration • Manual registration	Automatic Registration	Identical to Ikshana (K230249)
Medical Device Interfaces	• PACS Servers	• GE Vivid iq Premium Edition Ultrasound system • Compatible ultrasound probes • CIVCO eTRAX [K092619] • GE Omega V Angio table	• PACS Servers	Similar : Integrated with PACS system except XR90
Display Features	• 2D images: CT images • 3D models of segmented images • 3D models of patient skin images • Semi-transparent display of 3D/2D images on iPad) • Real-time augmented reality	• 2D CT images: CT images • 2D images: Ultrasound • 3D models of segmented images (Flashlight and Heads-up Display) • Semi-transparent display of 3D models and 2D Ultrasound images a hologram on HMD • Real-time augmented reality • Trajectories (Holographic Light Ray) • Trajectory Guidance (Holographic Needle Guide) • Virtual instrument's tip view (Light Ray) • 3D Off (only 2D)	• 2D images: CT images • 3D models of segmented images • 3D models of patient skin images • Semi-transparent display of 3D models and 2D images as hologram on HMD • Real-time augmented reality • Holographic annotations for surgical planning	Similar

	Proposed Device	Primary Predicate	Secondary Predicate	Remark
Device Name	**SKIA-Head (model: SKIA-ST00)**	**XR90 (Model: XR90-SYS)**	**Ikshana (ImmersiveAR)**	
510k number		**K223125**	**K230249**	
Manufacturer	**SKIA Inc.**	**MediView XR, Inc.**	**ImmersiveTouch**	
		• 3D follow instrument movement (Light Ray)		
Software Interface (GUI)	• Visualization control (show/hide virtual anatomy) • Patient Selection/Data Import • Buttons for registration • Software controls for images • Display of a semi-transparent 3D patient skin model (skin mesh) and CT images	• Visualization control (show/hide virtual anatomy & flashlight mode) • Patient Selection/Data Import • Buttons for registration • Adjust fusion via Adjustment method (point-to-point method) • Software controls for images • Target selection and planned trajectory management • Feedback on target/ultrasound alignment (Light Ray auditory and visual indicators)	• Visualization control (show/hide virtual anatomy, including multiple anatomical layers) • Patient Selection/Data Import • Buttons for registration • Software controls for images (segmentation, measurements, and annotations) • Pre-operative planning tools (bone alteration, implant templating, and virtual drawing) • Gesture-based controls for interacting with holograms (rotating, scaling, etc.)	Similar
Communication Between Imaging and Computing Hardware	• 2D DICOM images are imported from SKIA_Server on a hospital server computer to SKIA_Processor installed in the user's PC through Ethernet cable.	• 2D DICOM images imported through hospital-approved USB, CD, or DVD. • Real-time ultrasound image is captured by "Streamer" and transmitted **wirelessly** to the XR90's computing unit for real-time processing and fusion.	• 2D DICOM images are imported from a hospital server computer to the user's PC through Ethernet cable.	Similar
Communication Between Headset (or camera and iPad) and Computing Hardware	Wireless • Reconstructed 3D anatomy model is transmitted for registration and display on iPad using SKIA_Application through wireless communication. • Patient skin image is captured by 3D camera for registration in iPad.	Wireless • Reconstructed 3D anatomy model (fused holographic data) and virtual instrument guides are transmitted to the HMD (HoloLens 2) through wireless communication. • Streaming hardware (MediView Streamer and MediView Router) transmits US imaging from the scanner to the headset over LAN.	Wireless • Reconstructed 3D anatomy model is transmitted to Commercial VR headset for user's training & education. • The HMD (HoloLens 2) captures patient's visual data and transmits it to the user's PC for registration. • The computing unit then transmits the processed, aligned holographic data back to the headset for display.	Similar
Display and Optics Technology	The AR output image is displayed on iPad	Stereoscopic Holographic Display using near eye see-through holographic lenses/waveguides (Microsoft	• VR headsets used are having high-resolution **LCD or OLED panels** with A set of magnifying lenses, often	different

	Proposed Device	Primary Predicate	Secondary Predicate	Remark
Device Name	**SKIA-Head (model: SKIA-ST00)**	**XR90 (Model: XR90-SYS)**	**Ikshana (ImmersiveAR)**	
510k number		**K223125**	**K230249**	
Manufacturer	**SKIA Inc.**	**MediView XR, Inc.**	**ImmersiveTouch**	
		HoloLens 2)	Fresnel lenses for surgical training and planning. • Stereoscopic Holographic Display using near eye see-through holographic lenses/waveguides (Microsoft HoloLens 2)	
DICOM Compatible	Yes	Yes	Yes	Identical
Original 2D/3D image remains visible (acquisition data source)	Yes (CT)	Yes (CT, Ultrasound)	Yes (CT)	Identical to Ikshana (K230249)

Based on the above comparison, the SKIA-Head (SKIA-ST00) has similar intended use and technological and functional features as the predicate device in the principle of operation and supporting users with 3D visualization and image interaction with medical device images. Similar to the cited predicate devices, SKIA-Head (SKIA-ST00) is used for image viewing and interaction both prior to and during procedures. The SKIA-Head (SKIA-ST00) system is substantially equivalent to the predicate device with regard to the intended use and technological characteristics. Since the scope of equivalence for the SKIA-Head is limited to the intended use for pre-operative planning and general intra-operative display based on previously acquired CT data, differences between the SKIA-Head (SKIA-ST00) system and the predicates, such as ultrasound-guided needle procedures of XR90, do not introduce new questions of safety or efficacy. Also, differences in user interface, such as the use of a tablet PC versus a heads-up display, do not alter the fundamental safety or effectiveness profile of the device since these are a matter of form, not function. The core technology for visualizing and interacting with CT-based 3D images remains functionally equivalent for both devices, regardless of the display method. Therefore, it does not introduce a fundamental change in the device's function or risk profile, and the SKIA-Head is substantially equivalent to the predicate device.

Performance Data

Non-clinical verification and validation was performed in accordance with the following international standards,

A. Elecromagnetic Compatibility and Electrical Safety
   - IEC 60601-1:2005+A1:2012 Medical Electrical Equipment – Part 1; General Requirements for Basic Safety and Essential Performance
   - IEC 62366-1:2015+A1:2020 Medical devices Part 1: Application of usability engineering to medical devices

B. Software Verification and Validation
   - IEC 62304:2007 Medical Device Software – Software Life Cycle Processes
   - EN ISO 14971:2019 Medical devices - Applications of risk management to medical devices

C. DICOM Standard for the communication and management of medical imaging information
   - NEMPA PS 3.1~3.20 2024e

D. Device Performance
   - IEC 62563-1:2021, luminance-related display performance tests
   - Medical image management and processing system related to SAFETY of server and interface
   - verification of frame rate and registration accuracy

All the above tests were performed according to the test method and evaluated according to the acceptance criteria.

Conclusion

The subject device is substantially equivalent to the legally marketed predicate device based on the comparison information provided above and further extrapolated in the substantial equivalence comparison table. Verification testing, including system level tests, performance tests, and safety tests established the performance, functionality, and reliability characteristics of the system and demonstrated the proposed device does not introduce fundamentally new scientific technology. Therefore, it is concluded that the subject device described in this submission is substantially equivalent to the predicate device.