March 29, 2023

Mediso Medical Imaging Systems, Ltd.
% William McLain
Sr. Consultant
CRO Group, Inc.
342 E. Main Street, Suite 207
Leola, Pennsylvania 17540

Re: K221984
Trade/Device Name: InterView XP; InterView FUSION
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: February 24, 2023
Received: February 27, 2023

Dear William Mclain:

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,

Daniel M. Krainak, Ph.D.
Assistant Director
Magnetic Resonance and Nuclear Medicine Team
DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices
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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)*
K221984

Device Name
InterView XP

Indications for Use *(Describe)*
InterView XP is a Software as Medical Device (SaMD) aimed at reviewing medical images such as planar scans (Static, Whole Body, Dynamic, Multi-Gated) and tomographic scans (SPECT, Gated SPECT) acquired by gamma cameras. Review of other image modalities is also supported. Common Users for clinical purposes are trained medical professionals, including clinicians and technicians in hospitals or imaging centers. Software components provide functions for image display, manipulation, enhancements, analysis and quantification. This device is not indicated for mammography use or dental diagnostics. The software provides diagnostic information, however, diagnostic decision cannot be based solely on the software. InterView XP has no specific target population.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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)*
K221984

Device Name
InterView FUSION

Indications for Use *(Describe)*
InterView FUSION is a Software as Medical Device (SaMD) aimed at reviewing medical im- ages such as planar scans and tomographic scans from SPECT, PET, CT, and MRI modalities. Review of other image modalities is also supported. The common users for clinical purposes are trained medical professionals, including clinicians and technicians in hospitals or imaging centers. Software components provide functions for image display, manipulation, enhancements, analysis, and quantification. This device is not indicated for mammography use or dental diagnostics. The software provides diagnostic information — however, diagnostic decisions cannot be based solely on this software. InterView FUSION has no specific target population.

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)

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510(k) Summary - InterView XP

Submission Owner and Correspondent

Submission Owner

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Date Summary Prepared

February 23, 2023

Device Trade Name

InterView XP

Device Common Name

Medical Image Visualization And Post-processing Software As Medical Device (SaMD)

Device Classification Name

Medical Image Management and Processing System Classified as Class 2 at 21 CFR 892.2050, product code LLZ.

Legally Marketed Device To Which The Device Is Substantially Equivalent

The InterView XP is substantially equivalent to the Xeleris V Processing and Review Systems cleared under K201103.

Description of the Device

InterView XP is a DICOM image visualization and post-processing Software as Medical Device (SaMD). It is a standalone medical device. Developed by Mediso Medical Imaging Systems, built on state-of-the-art technologies, providing evaluation method according to the international guidelines for planar, whole body and SPECT nuclear medicine applications. The product is designed as a software only product, operating on Windows based OS. The software inputs are images of nuclear medicine studies that are DICOM 3.0 compatible and uploaded into the user's computer and the Software will process the images in multiple ways to achieve the image analysis by the user's demands.

General evaluation

General evaluation is a special procedure that has no predefined workflow steps. This procedure offers various tools that might be combined together to build a custom procedure. These tools are the same that are used in other procedures. Combined with user programming not only the workflow is customized but also the numerical results derived from processed data.

Indications for Use

InterView XP is a Software as Medical Device (SaMD) aimed at reviewing medical images such as planar scans (Static, Whole Body, Dynamic, Multi-Gated) and tomographic scans (SPECT, Gated SPECT) acquired by gamma cameras. Review of other image modalities is also supported. Common Users for clinical purposes are trained medical professionals, including clinicians and technicians in hospitals or imaging centers. Software components provide functions for image display, manipulation, enhancements, analysis and quantification. This device is not indicated for mammography use or dental diagnostics. The software provides diagnostic information, however, diagnostic decision cannot be based solely on the software. InterView XP has no specific target population.

Comparison Table with Predicate Device

The following Table compares the technological characteristics between the proposed InterView XP and the predicate Xeleris V Processing and Review Systems cleared under K201103.

Feature	Subject device InterView XP	Predicate device Xeleris V Processing and Review Systems (K201103)	Comparison
Intended use & Indications for use			
Intended Use	InterView XP is an advanced medical image visualization and post-processing Software as Medical Device (SaMD) for clinical applications. InterView XP is specialized for Nuclear Medicine applications focusing on planar, whole body and SPECT evaluations. InterView XP supports SPECT reconstruction. The process of quantitative evaluation is guided through standardized evaluation steps and supported by specialized viewers and automated algorithms. A wide range of function-specialized tools enable measurement, manipulation, enhancement and analysis of medical images. Data from Mediso or third party manufacturer's devices may be passed to the application from the integrated database or other PACS systems. Data handling includes images transfer, storage and printing capabilities of DICOM images. InterView XP is a stand-alone medical software which can operate on dedicated workstations provided by the manufacturer. InterView XP is NOT intended to be used as a replacement for visual interpretation nor as a diagnostic tool without other clinical and laboratory information. It is not intended to treat the patient, to monitor vital signs or to give a direct diagnosis of disease.	The system is intended for use by Nuclear Medicine (NM) or Radiology practitioners and referring physicians. The intended use of the system is to provide digital processing, review and reporting of medical images, including data display, quality control, image manipulation and quantification analysis, transfer, storage and printing capabilities. The system operates in a variety of configurations. The hardware components may include computer workstations, Communications devices, video monitors, data storage and hardcopy devices. Software components provide functions for performing operations related to image display; manipulation, enhancements, analysis and quantification and can operate on dedicated workstations and client-server architectures. (….)*	Similarities: · Each software is intended to be used for nuclear medicine applications. · Processing, review and reporting are the core functionalities. · Both are Software as Medical Device (SaMD) · Workstation or client-server architecture is supported. Differences: · N/A Intended use statement of InterView and Xeleris software are substantially equivalent.

Feature	Subject device InterView XP	Predicate device Xeleris V Processing and Review Systems (K201103)	Comparison
Indications for use	InterView XP is a Software as Medical Device (SaMD) aimed at reviewing medical images such as planar scans (Static, Whole Body, Dynamic, Multi-Gated) and tomographic scans (SPECT, Gated SPECT) acquired by gamma cameras. Review of other image modalities is also supported. Common Users for clinical purposes are trained medical professionals, including clinicians and technicians in hospitals or imaging centers. Software components provide functions for image display, manipulation, enhancements, analysis and quantification. This device is not indicated for mammography use or dental diagnostics. The software provides diagnostic information; however, diagnostic decision cannot be based solely on the software. InterView XP has no specific target population.	The system is intended for use by Nuclear Medicine (NM) or Radiology practitioners and referring physicians for display, processing, archiving, printing, reporting and networking of NMI data, including planar scans (Static, Whole Body, Dynamic, Multi-Gated) and tomographic scans (SPECT, Gated SPECT, dedicated PET or Camera-Based-PET) acquired by gamma cameras or PET scanners. The system can run on dedicated workstation or in a server-client configuration. The NM or PET data can be coupled with registered and/or fused CT or MR scans, and with physiological signals in order to depict, localize, and/or quantify the distribution of radionuclide tracers and anatomical structures in scanned body tissue for clinical diagnostic purposes.	Similarities: · Intended users are the same. · Software core functionalities are the same. · Both software process similar modalities. · Both software support stand-alone and client-server architecture. Differences: · N/A Indications for use statement of InterView and Xeleris software are substantially equivalent.
Field of use	General nuclear medicine processing methods in the field of Endocrinology, Cardiology, Osteology, Neurology, Nephrology, Hepatology, Gastroenterology, Pulmonology and other fields of nuclear medicine. SPECT reconstruction engine.	The system is intended for use by Nuclear Medicine (NM) or Radiology practitioners. Tools for general nuclear medicine including but not limited to applications for bone and cardiac, lung, renal, gallbladder, gastric brain, thyroid analysis. SPECT reconstruction methods included. Dosimetry applications.	Similarities: · Nuclear medicine applications. Differences: · *See detailed comparison below*. The field of use of InterView and Xeleris software is nuclear medicine. No impact on substantial equivalence.
Target population	No specifics target population.	Similarities: · Specifics target population is not defined. Differences: · N/A	Similarities: · No specific target population. Differences: · N/A. Neither InterView nor Xeleris has a specifics target population. No impact on substantial equivalence.

Feature	Subject device InterView XP	Predicate device Xeleris V Processing and Review Systems (K201103)	Comparison
Technical Characteristics			
Device design	Standalone Software with Graphical User Interface (GUI) controlled by the peripherals of the workstation. InterView family are post-processing software, and they have no control over the image generating devices.	Standalone Software with Graphical User Interface (GUI) controlled by the peripherals of the workstation. Xeleris is a post-processing software and has no control over the image generating devices.	Similarities: · Both softwares are GUI based software applications. · Basic operational principles are similar. · Neither software has impact on the Image generating device. Differences: · N/A Device design of InterView and Xeleris software are substantially equivalent.
Host environment	Operates in a single user environment, on a stand-alone workstation, or multi-user environment, on a server using Windows Remote Desktop Protocol. Single user and client operation system are Windows 10, server operation system is Windows Server 2019.	The system can run on dedicated workstation or in a server-client configuration deployed on a virtual server. Single user and client operation system are Windows 10, server operation system is Windows Server 2016.	Similarities: · Normal workstation and server configurations. · Each software is based on Windows Operating System. Differences: · Different version of server operating system. · Xeleris support virtualization. Different operating system version and virtualization are not considered as a significant technological difference. No impact on substantial equivalence.

Feature	Subject device InterView XP	Predicate device Xeleris V Processing and Review Systems (K201103)	Comparison
Image communication and I/O	Communication (I/O) conforms to the NEMA PS3 Digital Imaging and Communications in Medicine (DICOM) Standard. Supported modalities are CT, SPECT.	Communication (I/O) conforms to the NEMA PS3 Digital Imaging and Communications in Medicine (DICOM) Standard. DICOM 3.0 support for Nuclear Medicine and PET image and secondary capture image storage and query/retrieve as an SCU and SCP. Provides the ability to query/retrieve or receive DICOM 3.0 Nuclear Medicine Image data or secondary capture image data from GE Nuclear Medicine and PET/CT scanners. Provides support for DICOM 3.0 CT and MR Image data storage as a SCP and receive and send DICOM 3.0 CT/MR data from compatible CT, MR or PACS systems	Similarities: · Conformance to the NEMA PS3 Digital Imaging and Communications in Medicine (DICOM) Standard. · Supported modalities include PET, SPECT, CT and MR. Differences: · Besides the core modalities, other supported modalities might be different. As core modalities for nuclear medicine applications supported, other supported modalities are not considered as a significant technological difference. No impact on substantial equivalence.
Software functions and features			
General Tools	I/O, patient browser Display, viewers, workspaces, layouts Palette Measurement Image processing & modification Curves, graphs Customization	I/O, patient browser Display, viewers, workspaces, layouts Palette Measurement Image processing & modification Curves, graphs Customization	Both InterViewXP and Xeleris offer general tools for data processing, image viewing and manipulation, and curve fitting. There are minor differences in terms of how this information is presented none of which have a negative impact on substantial equivalence.

Feature	Subject device InterView XP	Predicate device Xeleris V Processing and Review Systems (K201103)	Comparison
SPECT reconstruction	Detect and correct motion; preview result;	· Sinogram and linogram images for QC analysis; automatic gated and non-gated SPECT motion correction; tools for manual adjustment and correction	Similarities: · Quality control before reconstruction. · Conventional reconstruction methods. · Reorientation methods. Differences: · Iterative reconstruction algorithm. InterView and Xeleris has a different implementation of 3D iterative OSEM reconstruction that are based on the modelling of the same physical principles (attenuation, scatter correction); therefore it can be considered as substantially equivalent.
	Range; simultaneous reconstruction; reconstruction algorithms; iterative reconstruction; attenuation correction; material map for CT AC; manual registration; automatic registration; change AC; filters; reconstruction profiles;	Side-by-side reconstruction and auto reformat; filtered back projection; iterative reconstruction w/scatter correction and/or attenuation correction (where relevant data is provided); 3D Post-Filter; Chang Attenuation Correction; comprehensive review of all slice planes, 3-plane spot collection and triangulation to show image interrelationships;	
	Manual reorientation; automatic reorientation; simultaneous reorientation; reoriented image parameters	· Supports reformat; oblique slices;	
Clinical procedures - Cardiology	Myocardial Perfusion SPECT; Myocardial Perfusion Gated SPECT; Gated blood pool SPECT; Thallium-201 chloride or [99mTc] labelled SESTAMIBI or Tetrofosmin; visual assessment; perfusion, wall motion, and thickening on polar maps;circumferential profile curves; global and regional ejection fraction; end-diastolic and end-systolic left ventricular volumes and stroke volume; launch third-party software;	Cardiac SPECT, gated SPECT, and PET data including Sestamibi, Thallium, Tetrofosmin, Dual Isotope, FOG, and Rubidium; review beating heart slices; Calculation of TID and lung heart ratio; Polar Plots and Reversibility Polar Plots; ejection fraction; masking; cardiac review screen; including 3D, Polar Maps, four sets, five slices review, ED/ES review, beating slices, EF, side-by-side perfusion and beating gated review; Synchronized gated slice beating; Direct linkage with optional 3rd party packages	Similarities: · Myocardial Perfusion SPECT analysis. · First-pass radionuclide angiography analysis. · Equilibrium gated planar radionuclide ventriculography analysis. Differences: · Gated blood pool SPECT analysis. · Minor differences in the processing methods. InterView and Xeleris provide clinical procedures for cardiac analysis. Although
	Gated blood pool SPECT; ventricle function on phase, motion and amplitude polar maps; phase histogram and volume curve; global and regional ejection fraction	N/A (with third party cardiac SW)	

Feature	Subject device InterView XP	Predicate device Xeleris V Processing and Review Systems (K201103)	Comparison
	First-pass radionuclide angiography; visual assessment; vena cava sup. transit time for quality control; cardiac output; Stroke volume; Mean Pulmonary Transit Time; Pulmonary Circulation Time; left to right shunt ratio	EF analysis with volume curve; left/right ventricle selection; auto/manual ROIs for systole and diastole; interactive beat selection; phase/Amplitude analysis; quality control review screen including transit times; pulmonary to system flow Used to determine the existence and size of the inter-cardiac shunts	there might be some difference in the processing methods and the derived parameters (e.g. intermediate results are also displayed) cardiac processing of both software can be considered as substantially equivalent. For gated blood pool SPECT analysis see reference device.
	Equilibrium gated planar radionuclide ventriculography analysis; visual assessment; global ejection fraction; ejection and filling time; average heart cycle and heart rate, and the lower/upper limit of the R–R interval	Peak Filling Rate protocol that includes the left ventricle (LV) emptying index and determines several timing, ejection fraction and rate parameters	
Clinical procedures - Endocrinology	Thyroid [99mTc]-Pertechnetate uptake, weight, and geometry; Thyroid Iodine uptake, weight and geometry; visual assessment; normalized uptake; thyroid weight; estimation of activity to be administered for the radioiodine therapy	Thyroid uptake index; 99mTc and I-131 static studies; statistics on the entire thyroid per thyroid lobe, or by region (cold or hot spot)	Similarities: · Thyroid uptake & geometry analysis. Differences: · Thyroid I-123 clearance. Thyroid I-123 clearance analysis procedure is based on general principles for evaluating a series of static planar studies, similar to dynamic planar processing. Activity changes over time of regions are visualized and parameters of the time activity curves are calculated. No specific clinical parameters are derived. Although this procedure is not present in Xeleris, this is not considered as a significant difference between the two products. No impact on substantial equivalence.
	Parathyroid dual label; [^{99m}Tc] MIBI, tetrofosmin, or thallium-chloride, the other with [^{123}I]NaI or [^{99m}Tc] pertechnetate; visual assessment both the thyroid and abnormal parathyroid tissue; normalized difference image	Parathyroid imaging analysis; dual isotope (99mTc & 201Tl); dual phase MIBI	
	Thyroid I-123 clearance; [123I] sodium-iodide; visual assessment; clearance calculated from the time activity curve	N/A	

Feature	Subject device InterView XP	Predicate device Xeleris V Processing and Review Systems (K201103)	Comparison
Clinical procedures - Exocrinology	Dacryo Scintigraphy; [99mTc]-Pertechnetate or [99mTc] colloid; visual assessment; Analysis of the time activity curve	N/A	Similarities: · N/A Differences: · Dacryo Scintigraphy analysis. Dacryo Scintigraphy analysis procedure is based on general principles for evaluating a dynamic planar study. Activity changes over time of regions are visualized and parameters of the time activity curves are calculated. No specific clinical parameters are derived. Although this procedure is not present in Xeleris, this is not considered as a significant difference between the two products. No impact on substantial equivalence.
Clinical procedures - Gastroenterology	Salivary glands; [99mTc]-Pertechnetate; visual assessment; uptake, extraction fraction;	N/A	Similarities: · Esophagus analysis. · Gastric analysis. Differences: · Salivary gland analysis. Salivary gland analysis procedure is based on general principles for evaluating a dynamic planar study. Activity changes over time of regions are visualized and parameters of the time activity curves are calculated. No specific clinical parameters are derived. Although this procedure is not present in Xeleris, this is not considered as a significant difference between the two products. No impact on substantial equivalence.
	Esophagus; [99mTc]-DTPA or [99mTc] colloid; visual assessment; transit time; transport speed, reflux analysis on condensed images, time activity curve	Esophageal Motility Analysis; analysis of esophageal dynamic studies via transit curves and compressed images; check the pass of a bolus along the esophagus; visualize reflux	
	Gastric emptying; [99mTc]-DTPA or [99mTc] colloid; residual activity; residual delayed activity; activity changes over time	Gastric emptying; gastric emptying curve; other parameters	

Feature	Subject device InterView XP	Predicate device Xeleris V Processing and Review Systems (K201103)	Comparison
Clinical procedures - Hepatology	Cholescintigraphy; [99mTc]-labeled IDA derivatives; visual assessment; time activity curves; parameters derived from curves; gallbladder ejection fraction;	Gallbladder EF; ejection fraction; motion correction;	Similarities: · Gallbladder analysis. Differences: · Liver first pass · Minor differences in the processing methods Static liver and spleen analysis procedure is based on general principles for evaluating a static planar study. Static liver and spleen calculate a simple activity ratio of the liver and spleen region. Liver first pass analysis procedure is based on general principles for evaluating a dynamic planar study. Activity changes over time of regions are visualized and parameters of the time activity curves are calculated. No specific clinical parameters are derived. Although these procedures are not present in Xeleris, this is not considered as a significant difference between the two products. No impact on substantial equivalence.
	Static liver and spleen; [99mTc] sulfur colloid; visual assessment; descriptive statistics;	N/A	
	Liver first pass; [99mTc]-labeled IDA derivatives; visual assessment; hepatic perfusion index; time activity curves; parameters derived from curves	N/A	

Feature	Subject device InterView XP	Predicate device Xeleris V Processing and Review Systems (K201103)	Comparison
Clinical procedures - Nephrology	Dynamic Kidney; [Tc-99m] labeled DTPA, [Tc-99m] labeled MAG3, Tc-99m] labeled EC, [I-131] labeled OIH, [I-123] labeled OIH derivatives; visual assessment; time activity curves; parameters derived from curves; split renal function (integral, Patlak-Rutland method); transplanted kidney perfusion and function index; Hilson index; residual and normalized residual kidney activity (NORA); output efficiency; renal blood flow (RBF/CO); diuretic response; deconvolution and Patlak-Rutland plot analysis; urine flow rate; residual urine volume; gravity-assisted and post-void drainage parameters; parametric images: time of maximum, maximal counts, mean transit time	Renal analysis; renal perfusion; renal function; automatically identify kidney ROIs with manual adjustments; renogram for diuretic and captopril acquisitions; DTPA, MAG3 and LASIX renography; DMSA Renal; pediatric kidney depth calculation; analysis methods include Gates GFR, QuantEM (Option); modified Gates, modified Schlegal; single sample clearance include Dubovsky (for Ortho Iodo hippuran and 99mTc-MAG3) and Bubeck (99mTc-MAG3); perfusion methods include Hilson, Peter, and Kirchner; relative uptake methods include Slope and Integral methods; excretion index (20 min,30 min, residual); Manchester with Rutland slope for relative uptake support	Similarities: · Dynamic kidney analysis. · Static kidney analysis. Differences: · Minor differences in the processing methods. InterView and Xeleris provide clinical procedures for kidney analysis. Although there might be some difference in the processing methods and the derived parameters (e.g. intermediate results are also displayed) kidney processing of both software can be considered as substantially equivalent.
	Static Kidney; [99mTc] labeled DMSA-derivatives; visual assessment; split renal function; uptake of the kidneys; different kidney depth estimation methods	Renogram DMSA; relative and absolute function (%dose); three methods of entry of dose (camera, well counter, and dose calibrator); five methods of kidney depth estimation (manual, Raynaud, Taylor, Tonnensen, and conjugate view)	
Clinical procedures - Neurology	Brain fist-pass; [99mTc] HMPAO, [99mTc] RBC; visual assessment; mean transit time; perfusion; time activity curves; parameters derived from curves	N/A	Similarities: · Brain perfusion analysis. · DaTscan analysis. Differences:

Feature	Subject device InterView XP	Predicate device Xeleris V Processing and Review Systems (K201103)	Comparison
	Brain perfusion; [99mTc] HMPAO; visual assessment; regional analysis	CBF Segmentation Protocol; Trans-axial slice subdivided into equiangular sectors over 360 degrees; Brain oblique reformatting; OM line definition with external marker; analysis of mean count, total count, maximum pixel value and standard deviation; Early/Late and Right/Left Mean ratios - Quality control of reconstructed data; image slice comparisons	· Brain first-pass. · Normal database of age matched reference values. · Minor differences in the processing methods. InterView and Xeleris provide clinical procedures for brain perfusion and DaTscan analysis. Although there might be some difference in the processing methods and the derived parameters (e.g. intermediate results are also displayed) brain perfusion and DaTscan processing of both software can be considered as substantially equivalent. Normal database of age matched reference values is not available in InterView but supported in the third-party software that are optionally provided with InterView. This functionality allows better interpretation of results but processing of DaTscan brain images is possible even without a normal database. Brain first pass analysis procedure is based on general principles for evaluating a dynamic planar study. Activity changes over time of regions are visualized and parameters of the time activity curves are calculated. No specific clinical parameters are derived. Although this procedure is not present in Xeleris, this is not considered as a significant difference between the two products. No impact on substantial equivalence.
	DaTscan; I-123 DaTscan; visual assessment; Statistics (mean counts, area…) of the striatal regions; count ratios	DaTQUANT optional application; visual evaluation and quantification of I-123-ioflupane images; elative comparison of uptake ratios; pre-defined VOI template; database of age matched reference values	

Feature	Subject device InterView XP	Predicate device Xeleris V Processing and Review Systems (K201103)	Comparison
Clinical procedures - Osteology	Whole body bone; visual assessment; basic statistics;	Whole Body and Bone Spots Review; Review whole body and spot images; dual zoom mode; predefined automatic layouts; regional masking; ROI comparison-based analysis; statistic and count display;	Similarities: · Whole body analysis. · 3-Phase Bone Scintigraphy analysis. · Sacroiliac index analysis. Differences: · Minor differences in the processing methods. InterView and Xeleris provide clinical procedures for bone analysis. Although there might be some difference in the processing methods and the derived parameters (e.g. intermediate results are also displayed) bone processing of both software can be considered as substantially equivalent.
	3-Phase Bone Scintigraphy; [99mTc]-labelled diphosphonates; visual assessment; uptake ratio of two regions;	Analysis of the perfusion and blood pool phases; ROI comparison-based analysis; statistic and count display;	
	Sacroiliac Index; [99mTc]-labelled diphosphonates; visual assessment; sacroiliac joint-to-sacrum ratios; left-to-right (or right-to-left) sacroiliac count ratio	Sacroiliac ratio with manual or auto edge detection	
Clinical procedures - Pulmonology	Lung Quantitative 6-Part; [99mTc] MAA, [99mTc] DTPA, Kr-81, Xe-133, Xe-127; visual assessment; basics statistics;	N/A	Similarities: · Lung ventilation and perfusion analysis. Differences: · Lung shunt fraction. · Lung quantitative 6 part Lung shunt fraction and lung quantitative 6-Part analysis procedure is based on general principles for evaluating a static
	Combined Lung; Lung Quantitative 6-Part; [99mTc] MAA, [99mTc] DTPA, Kr-81, Xe-133, Xe-127; visual assessment;	Lung analysis; analysis of lung ventilation and perfusion; ventilation index and quantitative perfusion analysis including ratio; templates for lung segments visualization;	
		N/A	

Feature	Subject device InterView XP	Predicate device Xeleris V Processing and Review Systems (K201103)	Comparison
	Lung shunt fraction; [99mTc] MAA; visual assessment; lung shunt index;		planar study. Lung shunt fraction calculates a simple activity ratio of the lung and liver region (total lung counts) / (total lung counts + total liver counts). Lung quantitative 6-Part simple calculates activities in 6 regions of the lung. Although these procedures are not present in Xeleris, this is not considered as a significant difference between the two products. No impact on substantial equivalence.

* Indication for use of the dedicated applications of GE Xeleris system is not included in the comparison, only the general part.

Non-Clinical Testing

Nonclinical testing consisted of a software validation that traced and tested all identified inputs and requirements. This testing consisted of the establishment of User Needs, Functional System Requirement, and Component Requirement Specifications. Test cases were executed to verify that these requirements were fulfilled. Clinical effectiveness was assessed through the completion of Functional Design Validations and Usability Validations. Acceptance criteria were fulfilled. Testing was based on:

- IEC 62304:2006 + A1/2015, Medical device software. Software life-cycle processes
- IEC 62366-1:2015, Medical devices. Part 1: Application of usability engineering to medical devices
- ISO 12052:2017, Health informatics. Digital imaging and communication in medicine (DICOM) including workflow and data management
- NEMA PS3, DICOM PS 3.x standard-series
- General Principles of Software Validation; Final Guidance for Industry and FDA Staff, Issued January 11, 2002

Clinical Testing

No clinical testing was performed in association with this submission.

Conclusions

In conclusion, the results of the comparison of design, materials, intended use and technological characteristics and the performance test demonstrate that the InterView XP is substantially equivalent to the predicate device.

510(k) Summary - InterView FUSION

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Date Summary Prepared

February 23, 2023

Device Trade Name

InterView FUSION

Device Common Name

Medical Image Visualization And Post-processing Software As Medical Device (SaMD)

Device Classification Name

Medical Image Management and Processing System Classified as Class 2 at 21 CFR 892.2050, product code LLZ.

Legally Marketed Device To Which The Device Is Substantially Equivalent

The InterView FUSION is substantially equivalent to the Xeleris V Processing and Review Systems cleared under K201103.

Description of the Device

InterView FUSION is a multi-modal visualization and evaluation software. Developed by Mediso built on state-of-the-art technologies, novel image processing algorithms and tools for evaluating different medical imaging modalities. The product is designed as a standalone software, i.e. Software as Medical Device (SaMD) product, operating on Windows OS as a classical user application.

Multi-modal registration and fusion of SPECT, PET, CT and MRI studies is a core functionality of InterView FUSION. Evaluation can be performed with the help of several specialized viewers and automated algorithms. Statistical measurements by ROIs, VOIs are present just as well as SUV representation for PET and even SPECT images. A wide range of function-specialized tools provide a well-detailed, fast and easy evaluation of medical images combining with advanced visualizations and interactions with flexible workspaces. Special segmentation methods provide quick and easy extraction of organs/regions from images. Basic arithmetic operations as well as spatial and frequency domain filters are also available.

Indications for Use

InterView FUSION is a Software as Medical Device (SaMD) aimed at reviewing medical images such as planar scans and tomographic scans from SPECT, PET, CT, and MRI modalities. Review of other image modalities is also supported. The common users for clinical purposes are trained medical professionals, including clinicians and technicians in hospitals or imaging centers. Software components provide functions for image display, manipulation, enhancements, analysis, and quan- tification. This device is not indicated for mammography use or dental diagnostics. The software provides diagnostic information — however, diagnostic decisions cannot be based solely on this software. InterView FUSION has no specific target population.

Technological Characteristics

The following Table compares the technological characteristics between the proposed InterView FUSION and the predicate Xeleris V Processing and Review Systems cleared under K201103.

Feature	Subject device InterView FUSION	Predicate device Xeleris V Processing and Review Systems (K201103)	Comparison
Intended use & Indications for use			
Intended Use	InterView FUSION is an advanced multi-modality medical image visualization and post-processing Software as Medical Device (SaMD) for clinical applications. Multi-modal registration and fusion of functional – SPECT, PET – and anatomical – CT, MRI – studies are a core functionality. Quantitative evaluation can be performed with the help of several specialized viewers, flexible workspaces and automated algorithms. A wide range of function-specialized tools enable measurement, manipulation, enhancement and analysis of the images. Data from Mediso or third-party manufacturer's devices may be passed to the application from the integrated database or other PACS systems. InterView FUSION is a stand-alone medical software. InterView FUSION is NOT intended to be used as a replacement for visual interpretation nor as a diagnostic tool without other clinical and laboratory information. It is not intended to treat the patient, to monitor vital signs or to give a direct diagnosis of disease.	The system is intended for use by Nuclear Medicine (NM) or Radiology practitioners and referring physicians. The intended use of the system is to provide digital processing, review and reporting of medical images, including data display, quality control, image manipulation and quantification analysis, transfer, storage and printing capabilities. The system operates in a variety of configurations. The hardware components may include computer workstations, Communications devices, video monitors, data storage and hardcopy devices. Software components provide functions for performing operations related to image display; manipulation, enhancements, analysis and quantification and can operate on dedicated workstations and client-server architectures. (….)*	Similarities: · Each software is intended to be used for nuclear medicine applications. · Processing, review and reporting are the core functionalities. · Both are Software as Medical Device (SaMD) · Workstation or client-server architecture is supported. Differences: · N/A Intended use statement of InterView and Xeleris software are substantially equivalent.
Indications for use	InterView FUSION is a Software as Medical Device (SaMD) aimed at reviewing medical images such as planar scans and tomographic scans from SPECT, PET, CT and MRI modalities. Review of other image modalities is also supported. Common Users for clinical purposes are trained medical professionals, including clinicians and technicians in hospitals or imaging centers. Software components provide functions for image display, manipulation,	The system is intended for use by Nuclear Medicine (NM) or Radiology practitioners and referring physicians for display, processing, archiving, printing, reporting and networking of NMI data, including planar scans (Static, Whole Body, Dynamic, Multi-Gated) and tomographic scans (SPECT, Gated SPECT, dedicated PET or Camera-Based-PET) acquired by gamma	Similarities: · Intended users are the same. · Software core functionalities are the same. · Both software process similar modalities. · Both software support stand-alone and client-server architecture.

Feature	Subject device InterView FUSION	Predicate device Xeleris V Processing and Review Systems (K201103)	Comparison
	enhancements, analysis and quantification. This device is not indicated for mammography use or dental diagnostics. The software provides diagnostic information, however diagnostic decision cannot be based solely on the software. InterView FUSION has no specific target population.	cameras or PET scanners. The system can run on dedicated workstation or in a server-client configuration. The NM or PET data can be coupled with registered and/or fused CT or MR scans, and with physiological signals in order to depict, localize, and/or quantify the distribution of radionuclide tracers and anatomical structures in scanned body tissue for clinical diagnostic purposes.	Differences: · N/A Indications for use statement of InterView and Xeleris software are substantially equivalent.
Clinical procedures -Lesion detection method	Lesion detection method; detection range; mask regions; global threshold method; local threshold method; lymph node package method	Q.Volumetrix AI; quantitative SPECT/PET results are further enhanced with advanced segmentation tools providing 2D and 3D organ and lesion characterization.	Similarities: · Lesion detection. Differences: · Minor differences in the processing methods. InterView and Xeleris provide a clinical procedure for lesion detection. Lesion detection is an advanced segmentation method that facilitates the segmentation of lesions (regions with higher activity on NM images). Different manual and automatic methods might be applied to find the proper lesion contour. Although there are differences in the applied techniques it shall be considered as substantially equivalent.
Clinical procedures -Follow-up method	Follow-up method; quality control; register images; compare images; copy baseline findings; propagate findings; overview findings; display results; manage follow-up finding	Q.Volumetrix AI; quantitative patient follow-up; two instances of the same application with two different studies of the same patient	Similarities: · Follow-up analysis. Differences: · Minor differences in the workflow InterView and Xeleris provide a clinical procedure for follow-up analysis that is comparing a patient earlier studied with the current ones. The essence

Feature	Subject device InterView FUSION	Predicate device Xeleris V Processing and Review Systems (K201103)	Comparison
			of the procedure is to provide a simple workflow that facilitates processing. Although there are differences in the workflow, it shall be considered as substantially equivalent.

Non-Clinical Testing

Nonclinical testing consisted of a software validation that traced and tested all identified inputs and requirements. This testing consisted of the establishment of User Needs, Functional System Requirement, and Component Requirement Specifications. Test cases were executed to verify that these requirements were fulfilled. Clinical effectiveness was assessed through the completion of Functional Design Validations and Usability Validations. Acceptance criteria were fulfilled. Testing was based on:

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Clinical Testing

No clinical testing was performed in association with this submission.

Conclusions

In conclusion, the results of the comparison of design, materials, intended use and technological characteristics and the performance test demonstrate that the InterView FUSION is substantially equivalent to the predicate device.