November 3, 2025

Pie Medical Imaging B.V.
Annemiek Bouts
Regulatory Affairs Coordinator
Philipsweg 1
Maastricht, Limburg 6227 AJ
Netherlands

Re: K250330
Trade/Device Name: 3mensio Workstation
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QIH, LLZ
Dated: September 29, 2025
Received: September 29, 2025

Dear Annemiek Bouts:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 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 systems (QS) regulation (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
Assistant Director
Imaging Software Team
DHT8B: Division of Radiologic 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.

Submission Number *(if known)*

K250330

Device Name

3mensio Workstation

Indications for Use *(Describe)*

Standalone software for medical image analysis intended for advanced visualization and quantitative analysis for diagnostics in the field of cardiology or radiology by means of enabling visualization and measurement of structures of the heart and vessels for:
- Pre-operational planning and sizing for cardiovascular interventions and surgery
- Postoperative evaluation
- Support of clinical diagnosis by quantifying dimensions in coronary arteries
- Support of clinical diagnosis by quantifying calcifications (calcium scoring)

To facilitate the above, the 3mensio Workstation provides general functionality such as:
- Segmentation of cardiovascular structures
- Automatic and manual centerline detection
- Visualization and image reconstruction techniques: 2D review, Volume Rendering, MPR, Curved MPR, Stretched CMRP, Slabbing, MIP, AIP, MinIP
- Measurement and annotation tools
- Reporting tools

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.

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510(k) Summary	K250330 3mensio Workstation	Pie Medical Imaging BV

I – General Information

Submitter/Owner Name	Pie Medical Imaging BV
Address	Demertdwarsstraat 8A01 , 6227 AK Maastricht, The Netherlands
Phone Number	+31 43 32 81 328
Contact Person	Annemiek Bouts, Regulatory Affairs Coordinator
Email Address	regulatory@pie.nl

Trade Name	3mensio Workstation	
Classification	Regulation Name:	Medical Image Management and Processing System
	Regulation Class:	Class II
	Regulation Number:	21 CFR 892.2050
	Classification Product Code:	QIH, LLZ
Predicate Devices	**Primary predicate device:** 3mensio Workstation (K153736, 21 CFR 892.2050, LLZ)	
	Secondary predicate device: TOMTEC-ARENA (K213544, 21 CFR 892.2050, LLZ, QIH)	

II - Device Description

3mensio Workstation is an image post-processing software package for advanced visualization and analysis for diagnostics in the field of cardiology and radiology and offers functionality to view CT/X-Ray angiographic and ultrasound images, to segment cardiovascular structures in these images and to analyze and quantify these cardiovascular structures and to present the results in different formats.

3mensio Workstation can be deployed as a web-based solution intended for usage in a network or cloud environment or as a standalone package and runs on a PC with a Windows operating system. It can read DICOM images from an accessible file system, hard disk (local directory), or (indirectly) received from the CT or PACS system. *3mensio Workstation* provides the functionality to import the DICOM images and to organize the loaded DICOM images into patients, studies, and series.

3mensio Workstation contains two analysis modules: 3mensio Vascular and 3mensio Structural Heart:

- 3mensio Vascular enables assessment of vessels and can help to measure calcifications, aneurysms and other anomalies to quickly and reliably prepare for various types of vascular procedures.
- 3mensio Structural Heart enables assessment and measurement of different structures of the heart, e.g., the heart valves, coronary arteries and the ventricles. It provides analysis of different approach routes to cardiovascular structures for replacement or repair procedures. In addition, it can help in the quantification of calcifications.

Results can be displayed on the screen, printed, or saved in a variety of formats to hard disk, network or PACS system. Results and clinical images with overlay can also be printed as a hardcopy and exported in various electronic formats.

III – Intended Use and Indications for Use

Intended Use

Standalone diagnostic bioimaging software is intended to measure and visualize cardiovascular structures.

Indications for Use

Standalone software for medical image analysis intended for advanced visualization and quantitative analysis for diagnostics in the field of cardiology or radiology by means of enabling visualization and measurement of the heart and vessels for:

- Pre-operational planning and sizing for cardiovascular interventions and surgery
- Postoperative evaluation
- Support of clinical diagnosis by quantifying dimensions of coronary arteries
- Support of clinical diagnosis by quantifying calcifications (calcium scoring)

To facilitate the above, the 3mensio Workstation provides general functionality such as:

- Segmentation of cardiovascular structures
- Automatic and manual centerline detection
- Visualization and image reconstruction techniques: 2D review, Volume Rendering, MPR, Curved MPR, Stretched CMPR, Slabbing, MIP, AIP, MinIP
- Measurement and annotation tools
- Reporting tools

IV - Substantial equivalence comparison

The devices 3mensio Workstation (K153736) and TOMTEC-ARENA (K213544) have been selected as predicate devices for *3mensio Workstation*. The selected devices have technological features and characteristics comparable to *3mensio Workstation* and are intended to be used by or under supervision of a cardiologist or radiologist to support clinical decision making of cardiovascular conditions.

The primary predicate device, 3mensio Workstation (K153736), is an earlier version of the current *3mensio Workstation* product. The indications for use of the two devices are similar. The two products provide the same functionalities for advanced visualization and measurements of structures of the heart, heart valves and vessels to assist in pre-operational planning and sizing for cardiovascular interventions and surgery and postoperative evaluation. Additionally they both feature functionality for segmentation of cardiovascular structures, quantify dimensions and calcifications in coronary arteries and have measurement and annotation tools. All these functionalities are supported in both the new *3mensio Workstation* product and the predicate device 3mensio Workstation (K153736). Therefore, the predicate device 3mensio Workstation (K153736) is selected as the primary predicate device.

The differences in technological characteristics between the predicate device K153736 and the device *3mensio Workstation* are that the new *3mensio Workstation* runs from a web browser intended for usage in a network or cloud environment. Predicate device K153736 is only a standalone usage device. Furthermore, *3mensio Workstation* includes calcium quantification of more cardiovascular structures than the predicate device K153736 which only included calcium quantification in the coronary arteries. In addition, the *3mensio Workstation* includes machine learning (ML) features for some of the functionalities already available in the primary predicate device.

Another difference between the previous generation of the *3mensio Workstation* product, 3mensio Workstation (K153736) and the current device is a workflow for mitral valve analysis on 3D ultrasound images (3D US mitral valve). The selected secondary predicate device, TOMTEC-ARENA (K213544), offers similar functionality and is therefore selected as a secondary predicate device. Both software applications use the same types of data and operating principles for the user and technology regarding data import, analysis, image display and storage of results.

A summary of the technological characteristics of the subject device and predicate devices is demonstrated in the Table below.

	Subject Device	**Primary predicate device**	**Secondary predicate device**	**Comparison**
Device Name	3mensio Workstation	3mensio Workstation	TOMTEC	/
510(k) Number	K250330	K153736	K213544	/
Product Code	QIH, LLZ	LLZ	LLZ, QIH	Similar, the subject device implements AI/ML algorithms
Classification	Medical image management and processing system	Medical image management and processing system	Medical image management and processing system	Same
Regulation Number	21 CFR 892.2050	21 CFR 892.2050	21 CFR 892.2050	Same
Intended Use	Standalone diagnostic bioimaging software is intended to measure and visualize cardiovascular structures.	3mensio Workstation is a software solution that is intended to provide Cardiologists, Radiologists and Clinical Specialists additional information to aid them in reading and interpreting DICOM compliant medical images of structures of the heart and vessels.	TOMTEC-ARENA software is a clinical software package designed for review, quantification and reporting of structures and function based on multi-dimensional digital medical data acquired with different modalities. TOMTEC-ARENA is not intended to	Same, both the subject device and primary predicate device generally share the intended use to enable visualization and measurement of cardiovascular structures.

		3mensio Structural Heart enables the user to: • Visualize and measure (diameters, lengths, areas, volumes, angles) structures of the heart and vessels • Quantify calcium (volume, density) 3mensio Vascular enables the user to: • Visualize and assess stenosis, aneurysms and vascular structures • Measure the dimensions of vessels (diameters, lengths, areas, volumes, angles)	be used for reading of mammography images.	
Indications for Use	Standalone software for medical image analysis intended for advanced visualization and quantitative analysis for diagnostics in the field of cardiology or radiology by means of enabling visualization and measurement of the heart and vessels for: • Pre-operational planning and sizing for cardiovascular interventions and surgery • Postoperative evaluation • Support of clinical diagnosis by quantifying dimensions of coronary arteries • Support of clinical diagnosis by quantifying calcifications (calcium scoring) To facilitate the above, the 3mensio Workstation provides general functionality such as: • Segmentation of cardiovascular structures • Automatic and manual centerline detection • Visualization and image reconstruction techniques: 2D review, Volume Rendering, MPR, Curved MPR, Stretched CMPR, Slabbing, MIP, AIP, MinIP • Measurement and annotation tools • Reporting tools	3mensio Workstation enables visualization and measurement of structures of the heart and vessels for: • Pre-operational planning and sizing for cardiovascular interventions and surgery • Postoperative evaluation • Support of clinical diagnosis by quantifying dimensions in coronary arteries To facilitate the above, the 3mensio Workstation provides general functionality such as: • Segmentation of cardiovascular structures • Automatic and manual centerline detection • Visualization and image reconstruction techniques: 2D review, Volume Rendering, MPR, Curved MPR, Stretched CMPR, Slabbing, MIP, AIP, MinI • Measurement and annotation too • Reporting tools	Indications for use of TomTec-Arena TTA2 software are quantification and reporting of cardiovascular, fetal, abdominal structures and function of patients with suspected disease to support the physician in the diagnosis.	Same for the subject device and primary predicate device. Additionally, the subject device includes functionality for calcium quantification in in other cardiovascular structures then only coronary arteries. For the secondary predicate device, only quantification and reporting of cardiovascular structures is applicable for this comparison. Other anatomical structures are not relevant for the comparison.
Anatomical Site	Segmentation, quantification, review, and reporting of cardiovascular structures	Segmentation, quantification, review, and reporting of cardiovascular structures	Segmentation, quantification, review, and reporting of cardiovascular, fetal and abdominal structures.	Same for the subject device and primary predicate device. For the secondary predicate device, only quantification and reporting

				of cardiovascular structures is applicable for this comparison. Other anatomical structures are not relevant for the comparison.
Design	Software as a medical device: standalone and web-based (on-premise and in the cloud)	Software as a medical device (standalone)	Software as a medical device (standalone)	The subject device can be deployed either standalone or web-based (on-premise and in the cloud) but this difference does not impact the intended use, indications for use, safety and performance of the device. Any risks related to web-based availability (both on-premise and in the cloud) are mitigated by cybersecurity measures.
Data Import and Type	• Vendor independent • CT data in DICOM format • X-Ray data in DICOM format • Ultrasound data (2D and 3D) in DICOM format	• Vendor independent • CT data in DICOM format • X-Ray data in DICOM format • Ultrasound data (2D) in DICOM format	• Vendor independent • Ultrasound data (2D and 3D) in DICOM format	Same, the subject device includes data types of both predicate device combined.
Data Management	• Study list overview • Deleting • Exporting • Anonymizing • Search	• Study list overview • Deleting • Exporting • Anonymizing • Search	Note: features not mentioned since they are not relevant for this comparison.	Same, the subject device and primary predicate device use the same types of data management functionality.
Image Processing and Contour Definition	• Realign orthogonal MPR's • Segmentation toolset: - Automatic segmentation (both AI and non-AI) - Manual segmentation - Automatic centerline - Manual centerline - Growing centerline - Centerline editing • Volume sculpting	• Realign orthogonal MPR's • Segmentation toolset: - Automatic segmentation (non-AI) - Manual segmentation - Automatic centerline - Manual centerline - Growing centerline - Centerline editing Volume sculpting	Note: features not mentioned since they are not relevant for this comparison.	Both the subject and primary predicate device include automated and manual segmentation functionality and both devices include the option for the physician to review and edit the segmentation. The segmentation toolset in the subject device additionally includes ML features.
Image Assessment	• Linear (length and diameter), area and angle measurements • Volume measurements • C-arm angulation calculation • Text, arrow and 3D annotations • Calcium scoring • Valve assessment	• Linear (length and diameter), area and angle measurements • Volume measurements • C-arm angulation calculation • Text, arrow and 3D annotations • Calcium scoring • Valve assessment	• Linear (length and diameter), area and angle measurements • Volume measurements • Text, arrow and 3D annotations	Same, the subject device and primary predicate device use the same image assessment functionality. Also the secondary predicate device uses relevant image assessment types for analysis of 3D ultrasound images.
Image Display	• Orthogonal, oblique, double-oblique, curved, cross-curved, stretched MPR, curved MPR views • MIP, AIP, MinIP and color volume slabs • Volume rendering • 2D slice review and stack comparison • 4D cine • Multi-tissue color and opacity control • Virtual device displays	• Orthogonal, oblique, double-oblique, curved, cross-curved, stretched MPR, curved MPR views • MIP, AIP, MinIP and color volume slabs • Volume rendering • 2D slice review and stack comparison • 4D cine • Multi-tissue color and opacity control Virtual device displays	• Oblique, double-oblique views • Volume rendering • 4D cine	Same, both the subject device and primary predicate device use the same types of image display. The secondary predicate device uses relevant image display features for analysis of 3D ultrasound images.
Storage and Export of Results	Session states PDF reports	Session states PDF reports	Not relevant for comparison.	Same.

V - Performance Data

Verification and validation of the *3mensio Workstation* showed that the system requirements – derived from the indications for use and defined user needs – as well as risk control measures were implemented correctly, and that the device meets its specifications including conformance to the international recognized process standards (i.e., ISO 13485, ISO 14971, IEC 62304, IEC 62366-1, and IEC 82304-1).

Documentation is provided as recommended by FDA's Guidance "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" and verification and validation was performed per the FDA Guidance "Technical Performance Assessment of Quantitative Imaging in Radiological Device Premarket Submission'. Performance testing was conducted where the results of automatically determined segmentation and measurements was evaluated against ground-truth values manually obtained by experts with the primary predicate device. The results showed high accuracy and agreement with the predicate device, meeting all predefined acceptance criteria. The performance tests included statistical methods such as Bland-Altman analysis, intraclass correlation coefficient (ICC) calculations and Dice coefficient.

Testing Characteristics

The performance testing was based upon a multi-centric observational cohort study involving MSCT datasets of 65 patients indicated for valvular intervention. The cohort comprised of at least 50% datasets from USA. The age range of the studied cohort was 38-99 years, with 50% female subjects. The cohort included CT scans from different CT manufacturers and covered imaging parameters such as different slice thickness and contrast enhancement. No datasets were included that were used for training the machine learning models.

Testing Methodology and Statistical Approach

The accuracy of the automatically determined segmentations was evaluated using Dice scores. The segmentations covered various cardiovascular structures including the aortic nadir positions, mitral annulus plane tricuspid annulus. The accuracy of automatically determined measurements was evaluated using Bland-Altman analysis and the intraclass correlation coefficient (ICC).

Segmentation Results

The resulting Dice scores ranged from 0.94 ± 0.07 for the mitral annulus, 0.87 ± 0.12 for the tricuspid annulus. The average distance from the automatically detected nadir positions towards the ground truth annular plane was -/- 0.64 ± 1.07 mm. These values demonstrate that a high accuracy is achieved for the automatically determined segmentations meeting the pre-defined acceptance criteria.

Measurements Results:

The ICC values were 0.99 for the measurements on the aortic annulus plane derived from the aortic nadir positions, 0.94 and above for the measurements on the mitral annulus and 0.97 and above for the measurements on the tricuspid annulus indicating excellent agreement with the ground-truth values obtained by experts. Bland-Altman analysis shows excellent agreement between the automatically determined measurements and the measurements obtained by experts.

Based on the above it can be concluded that the automatically determined segmentations and measurements are as accurate and reliable as those obtained using the predicate device. Overall, comparable performance was achieved on all variability factors including geographic location, scanners, slice thickness, age, and gender.

The verification and validation results demonstrate the safety and effectiveness of *3mensio Workstation* in relation to its intended use and indications for use and therefore *3mensio Workstation* can be considered as safe and effective as its predicate devices.

VI - Conclusion

Based on the application of risk management and performance testing inherent to PMI's QA system (compliant with recognized standards as stated above) the conclusion is that *3mensio Workstation* is as safe and effective as its predicate device in terms of indications for use, technological characteristics, measurements, and operating environment and does not raise any new issues related to safety and effectiveness compared to the predicate devices.