



Food and Drug Administration
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Pie Medical Imaging B.V.
% Ms. Annemeik Bouts
Regulatory Affairs Coordinator
Philipsweg 1
Maastricht 6227 AJ
THE NETHERLANDS

May 27, 2016

Re: K153736
Trade/Device Name: 3mensio Workstation
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: April 20, 2016
Received: May 2, 2016

Dear Ms. 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 (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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink that reads "Robert Ochs". The signature is written in a cursive, slightly slanted style.

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K153736

Device Name

3mensio Workstation

Indications for Use (Describe)

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
- Support of clinical diagnosis by quantifying calcifications (calcium scoring) in the 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, 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.

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Submitter/Owner Name	Pie Medical Imaging BV
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Email Address	annemiek.bouts@pie.nl
Preparation Date	16-dec-15
Trade Name	3mensio Structural Heart / 3mensio Vascular
Common Name	3mensio Workstation
Classification:	Classification Name: Image Processing System Classification Panel: Radiology Regulation Class: Class II Regulation number: 21 CFR 892.2050 Classification Product Code: LLZ
Predicate Devices	3mensio Workstation (K120367) Philips Intellispace Cardiovascular (K153022)
Device Description	<p>The 3mensio Workstation software allows cardiologists, radiologist and clinical specialists to select patient studies from various data sources, view them, and process the images with the help of a comprehensive set of tools. 3mensio Workstation works with all major medical image formats and can access multiple data stores and across networks.</p> <p>3mensio Workstation can combine 2D scan slices into comprehensive 3D models of the patient, and can display supporting ultrasound and X-ray Angio data. The software accurately represents different types of tissue, making it easier to diagnose anomalies in scans.</p> <p>3mensio Workstation contains two modules, 3mensio Structural Heart (containing submodule cCTA), and 3mensio Vascular which can be marketed in combination or as separate solutions:</p> <ul style="list-style-type: none">• 3mensio Structural Heart enables assessment and measurement of different structures of the heart, e.g. aortic valve, mitral valve and ventricles. It provides analysis of the feasibility of a transapical, transfemoral or subclavian approach to structures for replacement or repair procedures.<ul style="list-style-type: none">○ 3mensio cCTA enables assessment and measurement of the coronary arteries and can help in the quantification of the dimensions of the coronary arteries and of the calcified plaques present in coronary arteries.• 3mensio Vascular enables assessment of vessels and can help identify calcifications, aneurysms and other anomalies to quickly and reliably prepare for various types of vascular procedures.

The results can be displayed, printed or saved in a variety of formats to a hard disk, network, PACS system or CD. Results can also be printed as a hardcopy.

Intended Use

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. 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, aneurisms and vascular structures
- Measure the dimensions of vessels (diameters, lengths, areas, volumes, angles)

Indications for Use

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
- Support of clinical diagnosis by quantifying calcifications (calcium scoring) in the 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, MinIP
- Measurement and annotation tools
- Reporting tools

Technological Characteristics Comparison

A comparison of the technological characteristics of the predicate and subject device is given the table below.

	New Device	Predicate Device	Predicate Device
Device name	3mensio Workstation	3mensio Workstation	Intellispace Cardiovascular
Manufacturer	Pie Medical Imaging	Pie Medical Imaging	Philips
510(k) number	-	K120367	K153022
Intended Use and Indications for Use			
Intended use	<p>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.</p> <p>3mensio Structural Heart enables the user to:</p> <ul style="list-style-type: none"> • Visualize and measure (diameters, lengths, areas, volumes, angles) structures of the heart and vessels • Quantify calcium (volume, density) <p>3mensio Vascular enables the user to:</p> <ul style="list-style-type: none"> • Visualize and assess stenosis, aneurisms and vascular structures • Measure the dimensions of vessels (diameters, lengths, areas, volumes, 	<p>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.</p> <p>3mensio Structural Heart enables the user to:</p> <ul style="list-style-type: none"> • Visualize and measure (diameters, lengths, areas, volumes, angles) structures of the heart and vessels • Quantify calcium (volume, density) <p>3mensio Vascular enables the user to:</p> <ul style="list-style-type: none"> • Visualize and assess stenosis, aneurisms and vascular structures • Measure the dimensions of vessels (diameters, lengths, areas, volumes, 	<p>Philips IntelliSpace Cardiovascular software product is an integrated multimodality image and information system designed to perform the necessary functions required for import, export, storage, archival, review, analysis, quantification, reporting and database management of digital medical images.</p>

	New Device	Predicate Device	Predicate Device
Device name	3mensio Workstation	3mensio Workstation	Intellispace Cardiovascular
Manufacturer	Pie Medical Imaging	Pie Medical Imaging	Philips
510(k) number	-	K120367	K153022
	angles)	angles)	
Indications for Use	<p>3mensio Workstation enables visualization and measurement of structures of the heart and vessels for:</p> <ul style="list-style-type: none"> • 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 calcified plaques (calcium scoring) in the coronary arteries <p>To facilitate the above, the 3mensio Workstation provides general functionality such as:</p> <ul style="list-style-type: none"> • 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 	<p>3mensio Workstation enables visualization and measurement of structures of the heart and vessels for:</p> <ul style="list-style-type: none"> • Pre-operational planning and sizing for cardiovascular interventions and surgery • Postoperative evaluation <p>To facilitate the above, the 3mensio Workstation provides general functionality such as:</p> <ul style="list-style-type: none"> • 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 	<p>Philips IntelliSpace Cardiovascular software product is an integrated multimodality image and information system designed to perform the necessary functions required for import, export, storage, archival, review, analysis, quantification, reporting and database management of digital cardiovascular images, waveforms and data related to cardiology.</p> <p>Philips IntelliSpace Cardiovascular offers support for third party applications in order to enable the use of commercially available tools and specified applications for analysis, quantification and reporting. It allows multiple users fast access to, and exchange of specific and/or multiple cardiology exams.</p> <p>Philips IntelliSpace Cardiovascular software runs on standard information technology hardware and software, utilizing the standard information technology operating systems and user interface.</p> <p>Communication and data exchange are done using standard protocols.</p> <p>Philips IntelliSpace Cardiovascular will also be made available for use on specified Cardiovascular Monitoring Systems, which use suitable hardware components.</p> <p>The modular design allows configurability to tailor the image import, archive and communications solution to one's particular budgetary and performance needs. The number of modalities and reporting and/or viewing sites can be configured per system.</p>
Technological Characteristics			
Data type	<ul style="list-style-type: none"> • CT data in DICOM format (vendor independent) 	<ul style="list-style-type: none"> • CT data in DICOM format (vendor independent) 	<ul style="list-style-type: none"> • Any image modality data in DICOM format (vendor independent)
Input of Patient Data	<ul style="list-style-type: none"> • Manual through keyboard/mouse • Command line interface 	<ul style="list-style-type: none"> • Manual through keyboard/mouse • Command line interface 	<ul style="list-style-type: none"> • Manual through keyboard/mouse • Command line interface
Study list image functionality	<ul style="list-style-type: none"> • Exporting • Deleting • Anonymizing (no automatic deletion of original patient data) • Search 	<ul style="list-style-type: none"> • Exporting • Deleting • Anonymizing (no automatic deletion of original patient data) • Search 	Full patient/study list support
Centreline extraction	<ul style="list-style-type: none"> • Realign orthogonal MPRs • Segmentation toolset: <ul style="list-style-type: none"> - Automatic segmentation - Automatic centreline - Manual centreline 	<ul style="list-style-type: none"> • Realign orthogonal MPRs • Segmentation toolset: <ul style="list-style-type: none"> - Automatic segmentation - Automatic centreline - Manual centreline 	(Features not mentioned since they are not relevant for the equivalence)

	New Device	Predicate Device	Predicate Device
Device name	3mensio Workstation	3mensio Workstation	Intellispace Cardiovascular
Manufacturer	Pie Medical Imaging	Pie Medical Imaging	Philips
510(k) number	-	K120367	K153022
	<ul style="list-style-type: none"> - Centreline editing • Undo/redo operations • Volume sculpting 	<ul style="list-style-type: none"> - Centreline editing • Undo/redo operations • Volume sculpting 	
Image Assessment X-Ray	<ul style="list-style-type: none"> • Linear (length and diameter), angular and ROI measurements • Volume measurements • C-Arm angulation calculation • Text and arrow annotations • Calcium scoring for assessment of calcium in the aortic root • Calcium scoring for assessment of calcium in the coronary arteries • Segmentation and analysis of coronary artery tree centerline 	<ul style="list-style-type: none"> • Linear (length and diameter), angular and ROI measurements • Volume measurements • C-Arm angulation calculation • Text and arrow annotations • Calcium scoring in vasculature 	<ul style="list-style-type: none"> • Calcium scoring for assessment of calcium in the coronary arteries (HeartBeat CS module) <p>(Other features not mentioned since they are not relevant for the equivalence)</p>
Image Assessment – IVUS / OCT	<ul style="list-style-type: none"> • Orthogonal, oblique, double oblique, curved, cross-curved, stretched MPR rendering • MIP, AveIP, MinIP and color volume slabs • MIP volume rendering • Color volume rendering • Grayscale volume rendering • 2D slice review and stack comparison • 4D cine • Interactive VOI clipping • Multi-tissue color and opacity control • Active presets • User-defined presets 	<ul style="list-style-type: none"> • Orthogonal, oblique, double oblique, curved, cross-curved, stretched MPR rendering • MIP, AveIP, MinIP and color volume slabs • MIP volume rendering • Color volume rendering • Grayscale volume rendering • 2D slice review and stack comparison • 3D view • Interactive VOI clipping • Multi-tissue color and opacity control • Active presets • User-defined presets 	(Features not mentioned since they are not relevant for the equivalence)
DICOM support	<ul style="list-style-type: none"> • Compatible with all scanner vendor DICOM datasets • Storage SCP • Import DICOM files • DICOM compliance for CT, enhanced CT, MRI, enhanced MRI, XA, Nuclear Medicine, CR, SC, and Ultrasound images • Import from DICOMDIR • Storage SCU • Query/retrieve SCU • Automatic grouping of images into volumes • Windows printing or send to PACS 	<ul style="list-style-type: none"> • Compatible with all scanner vendor DICOM datasets • Storage SCP • Import DICOM files • DICOM compliance for CT, MRI, XA, Nuclear Medicine, CR, SC, and Ultrasound images • Import from DICOMDIR • Storage SCU • Query/retrieve SCU • Automatic grouping of images into volumes • Windows printing or send to PACS 	Full DICOM support (identical to or more extensive than new device)
Storage of Results	<ul style="list-style-type: none"> • Printout • Session state • PDF format • DICOM PDF report 	<ul style="list-style-type: none"> • Printout • Session state • PDF format • DICOM SC report 	(Features not mentioned since they are not relevant for the equivalence)
Operating System	Microsoft Windows	Microsoft Windows	Microsoft Windows

Conformance Standards The device complies with the following conformance standards:

- NEMA PS 3.1 – 3.20 (2011), Digital Imaging and Communication in Medicine (DICOM) Set. (Radiology)
- ISO 14971:2007 Medical devices – Application of risk management to medical devices

Performance Data

The verification and validation of the 3mensio Workstation functionality was performed according to the Design Control procedure. Verification of the

3mensio Workstation showed that the system requirements – derived from the intended use and indications for use – were implemented correctly, demonstrating the effectiveness of the device.

A validation plan for the final validation of the release build is created and was executed on the final build.

A test report comparing the numerical results of the device compared with the predicate devices is also available.

Substantial Equivalence The analysis workflows 3mensio Structural Heart and 3mensio Vascular in the previously cleared device 3mensio Workstation (K120367) are available in 3mensio Workstation and are the same in terms of intended use and indications for use and have the same technological characteristic. The difference between these two devices is that the workflow ‘3mensio cCTA’ has been added in 3mensio Workstation. With the addition of the ‘3mensio cCTA’ workflow, the new 3mensio Workstation is, like the predicate 3mensio Workstation (K120367), intended to support the interventional cardiologist and radiologist with diagnoses and assist them during intervention of cardiovascular conditions.

3mensio cCTA consists of 2 features: Calcium scoring for coronary vessels and coronary vessel measurement.

3mensio cCTA Calcium scoring is compared to the HeartBeat CS module of Philips Intellispace Cardiovascular (K153022), which has similar intended use and indications for use as the new device. HeartBeat CS also performs calcium scoring in coronary vessels on DICOM CT images, like the predicate device. Technologically and in terms of GUI interaction, both features are very similar.

3mensio cCTA Coronary vessel measurement is compared to the vascular measurement module of 3mensio Workstation (K120367). Both types of measurements produce the same results, are measured in the same type of images, and use the same techniques: perform measurement on areas in reconstructed cross-sectional images based on a 3D centreline. Technologically and in terms of GUI interaction, both features are very similar.

Conclusion From the comparison table and substantial equivalence analysis we conclude that the intended use and technological characteristics of 3mensio Workstation are substantially equivalent to a combination of the predicate device 3mensio Workstation (K120367) and the predicate device Philips Intellispace Cardiovascular (K153022). Based on the application of risk management and performance testing we conclude that 3mensio Workstation is as safe and effective as its predicate devices and does not raise any new issues related to safety and effectiveness compared to the predicate devices, and has a comparable performance.