 K122429

5. 510(k) SUMMARY (AUTOPLAQUE)

NOV 2 8 2012

This summary of safety and effectiveness is being submitted in accordance with 21CFR Part 807, Subpart E, section 807.92.

Submitter's name and contact information

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Date prepared

January 31st 2012

Trade Name, Common Name and Classification

Trade Name: Autoplaque add-on ORS Visual
Common Name: Image Processing System, Radiology, Software PACS
Classification: Picture Archiving and Communications System, Product code LLZ, Class II

Device Description

The Autoplaque add-on for medical device ORS Visual (K100335) is a post processing analysis software package designed to assist Radiologists, Cardiologists, and other clinicians in the evaluation and assessment of coronary lesions.

Autoplaque is a software post-processing package for the ORS Visual application (K100335). It provides analysis of the vessel lumen and wall and makes it easier to detect findings in the coronary vessels.

The Autoplaque add-on has been extensively tested on a variety of platforms by both members of the development and quality control team and by potential customers serving as beta testers. A hazard analysis has been conducted and the level of concern has been classified as moderate. The release version of the software passed all tests considered critical in terms of patient safety and demonstrated an overall acceptable performance for release as determined by the predefined release criteria.

Intended Use:

Autoplaque is intended to provide an optimized non-invasive application to analyze coronary anatomy and pathology and aid in determining treatment paths from a set of Computed Tomography (CT) Angiographic images.

Autoplaque is a post processing application option for the ORS Visual platform (K100335). It is a non-invasive diagnostic reading software add-on intended for use by cardiologists and radiologists as an interactive tool for viewing and analyzing cardiac CT data for determining the presence and extent of coronary plaques.

The software is not intended to replace the skill and judgment of a qualified medical practitioner and should only be used by people who have been appropriately trained in the software's functions, capabilities and limitations. Users should be aware that certain views make use of interpolated data. This is data that is created by the software based on the original data set. Interpolated data may give the appearance of healthy tissue in situations where pathology that is near or smaller than the scanning resolution may be present.

ORS Visual software (K100335) and the Autoplaque add-on must be installed on a suitable commercial computer platform. It is the user's responsibility to ensure the monitor quality and ambient light conditions are consistent with the clinical applications.

Typical users of ORS Visual (K100335) and Autoplaque are trained medical professionals, including but not limited to radiologists, clinicians, technologists, and others.

Substantially Equivalent Devices

Object Research Systems (ORS) Inc believes that Autoplaque add-on for ORS Visual is substantially equivalent to other commercially available products, specifically:

- Philips' Comprehensive Cardiac Analysis (CCA) Plaque (K092747)
- Vitrea Version 4.0 with SUREPlaque (K071331)

Feature	ORS Visual Autoplaque	SUREPlaque	Philips CCA
Computer Platform	Windows OS	same	same
DICOM compliance	DICOM 3.1	same	same
2D Imaging	Review of coronary structure in 2D with MPR, curved MPR and straighten view.	same	same
3D Imaging	Review of coronary structure in 3D volume rendering with interactive control	same	same
Measurement	2D measurement tools of vessel diameter and contour	same	same
Maximum Intensity Projection (MIP)	MIP with interactive control and clip planes	same	same
Multiplanar Reformatting (MPR)	MPR with oblique slicing and variable thickness slabbing	same	same
Quantify plaque burden	Yes	same	same
Quantify coronary remodeling	Yes	same	same

Feature	ORS Visual Autoplaque	SUREPlaque	Philips CCA
Lesion characterization	Either as calcified or non-calcified	same	same
Lumen segmentation	Semi automatic	Automatic	Automatic
Stenosis quantification	% area stenosis % diameter stenosis	Same	same
Prescription use	Yes	same	same
NCP volume	Yes	same	same
CP volume	Yes	same	same
Low-density NCP volume	Yes	same	same
Intended users	Trained professionals	same	same

Software

Software development for the Autoplaque add-on for ORS Visual software (K100335) follows documented processes for software design, verification and validation testing. A risk assessment has been completed to identify potential design hazards that could cause an error or injury based on the use of the quantification results. Appropriate steps have been taken to control all identified risks for this type of medical device.

Hazard Analysis

Hazard analysis on this product has been tested throughout the definition, design, coding and testing phases of product development and implementation. This process has emphasized:

- Identification of potential hazards, their causes and effects;
- Development of methodologies to control the occurrence of hazard and to constrain their effects; and
- Determine any effect on patient safety and system effectiveness.

The potential hazards associated with this software product re no different than those of other PACS components. These are primarily related to failure of computer system components, and may be variously obviated by decisions taken by the customers of this product. None of these failures are expected to materially contribute to patient death or injury

It is our opinion that there is no hardware or software component, operating in a properly configured environment, whose failure or latent design defect would be expected to result in death or injury of a patient. Thus the "Level of Concern" is Moderate.

Technological Characteristics

ORS Visual (K100335) is software that is used with computer hardware to read, render and analyze diagnostic medical images in a user environment. The device does not contact the patient, nor does it control any life sustaining devices. A physician, providing ample opportunity for competent human intervention, interprets images and information being displayed.

Conclusions

The Autoplaque add-on for ORS visual (K100335) has similar intended uses as the substantially equivalent devices and has very similar technological characteristics to those devices. Minor technological differences do not raise any new questions regarding safety or effectiveness of the device. Thus, Autoplaque add-on for ORS visual (K100335) is substantially equivalent to the commercially available devices (see section 12).

The Autoplaque add-on for the ORS Visual software (K100335) has been extensively tested on a variety of platforms by both members of the development and quality control team and by potential customers serving as beta testers. A hazard analysis has been conducted and the level of concern has been classified as moderate. The release version of the software will be required to pass all tests considered critical in terms of patient safety and demonstrate an overall acceptable performance for release as determined by the predefined release criteria.

As specified in the proposed labeling and indications of use, the devices do not support mammographic and compressed images for viewing. Therefore, since the devices do not use compression technique that can result in the loss of data, no measurement of the error of the compressed image relative to the original has been performed (see section 18).

 K122429

5. 510(k) SUMMARY (VESSEL ANALYSIS)

This summary of safety and effectiveness is being submitted in accordance with 21CFR Part 807, Subpart E, section 807.92.

Submitter's name and contact information
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Date prepared
January 31st 2012

Trade Name, Common Name and Classification
Trade Name: Vessel Analysis add-on ORS Visual
Common Name: Image Processing System, Radiology, Software PACS
Classification: Picture Archiving and Communications System, Product code LLZ, Class II

Device Description

The Vessel Analysis add-on (Vessel Analysis) for medical device ORS Visual (K100335) is a post processing analysis software package designed to assist Radiologists, Cardiologists, and other clinicians in the evaluation and assessment of vascular anatomy.

Vessel Analysis is a software post-processing package for the ORS Visual application (K100335). It is an additional tool for the analysis of 2D/3D CT Angiographic images/data providing a number of display, measurements and batch filming/archive features to study user-selected vessels which include but are not limited to stenosis analysis, thrombus, pre/post stent procedures and directional vessel tortuosity visualization.

The Vessel Analysis add-on has been extensively tested on a variety of platforms by both members of the development and quality control team and by potential customers serving as beta testers. A hazard analysis has been conducted and the level of concern has been classified as moderate. The release version of the software passed all tests considered critical in terms of

patient safety and demonstrated an overall acceptable performance for release as determined by the predefined release criteria.

Intended Use:

Vessel Analysis is intended to provide an optimized non-invasive application to analyze vascular anatomy and pathology and aid in determining treatment paths from a set of Computed Tomography (CT) Angiographic images.

Vessel Analysis is a post processing application option for the ORS Visual platform (K100335) family of products and can be used in the analysis of 2D/3D CT Angiography images/data derived from DICOM 3.0 compliant CT scans for the purpose of cardiovascular and vascular disease assessment. This software is designed to support the physician in assessment of stenosis analysis, pre/post stent procedure and directional vessel tortuosity visualization.

Vessel Analysis automatic visualization tools provide the users with the capabilities to facilitate segmentation of bony structures for accurate identification of the vessels. Once vessels are visualized, tools are available for sizing the vessel, analyzing calcified and non-calcified plaque to determine the densities of plaque, measure areas of abnormalities within a vessel.

The software is not intended to replace the skill and judgment of a qualified medical practitioner and should only be used by people who have been appropriately trained in the software's functions, capabilities and limitations. Users should be aware that certain views make use of interpolated data. This is data that is created by the software based on the original data set. Interpolated data may give the appearance of healthy tissue in situations where pathology that is near or smaller than the scanning resolution may be present.

ORS Visual software (K100335) and the Vessel Analysis add-on must be installed on a suitable commercial computer platform. It is the user's responsibility to ensure the monitor quality and ambient light conditions are consistent with the clinical applications.

Typical users of ORS Visual (K100335) are trained medical professionals, including but not limited to radiologists, clinicians, technologists, and others.

Substantially Equivalent Devices

Object Research Systems (ORS) Inc believes that Vessel Analysis add-on for ORS Visual is substantially equivalent to other commercially available products, specifically:

- GE Advanced Vessel Analysis II (K060779)
- Vital Images Vitrea 4.0 (Vessel probe) (K071331)

Feature	ORS Visual Vessel Analysis	AVA II	Vital Images
Computer Platform	Windows OS	same	same
DICOM compliance	DICOM 3.1	same	same
2D Imaging	Review of vascular structure in 2D with MPR, curved MPR and straighten view.	same	same
3D Imaging	Review of vascular	same	same

Feature	ORS Visual Vessel Analysis	AVA II	Vital Images
	structure in 3D volume rendering with interactive control		
Measurement	2D measurement tools of vessel diameter and contour	same	same
Maximum Intensity Projection (MIP)	MIP with interactive control and clip planes	same	same
Multiplanar Reformatting (MPR)	MPR with oblique slicing and variable thickness slabbing	same	same
Prescription use	Yes	same	same
Intended users	Trained professionals	same	same

Software

Software development for the Vessel Analysis add-on for ORS Visual software (K100335) follows documented processes for software design, verification and validation testing. A risk assessment has been completed to identify potential design hazards that could cause an error or injury based on the use of the quantification results. Appropriate steps have been taken to control all identified risks for this type of medical device.

Hazard Analysis

Hazard analysis on this product has been tested throughout the definition, design, coding and testing phases of product development and implementation. This process has emphasized:

- Identification of potential hazards, their causes and effects;
- Development of methodologies to control the occurrence of hazard and to constrain their effects; and
- Determine any effect on patient safety and system effectiveness.

The potential hazards associated with this software product are no different than those of other PACS components. These are primarily related to failure of computer system components, and may be variously obviated by decisions taken by the customers of this product. None of these failures are expected to materially contribute to patient death or injury

It is our opinion that there is no hardware or software component, operating in a properly configured environment, whose failure or latent design defect would be expected to result in death or injury of a patient. Thus the "Level of Concern" is Moderate.

Technological Characteristics

Vessel Analysis add-on for ORS Visual (K100335) is software that is used with computer hardware to read, render and analyze diagnostic medical images in a user environment. The device does not contact the patient, nor does it control any life sustaining devices. A physician, providing ample opportunity for competent human intervention, interprets images and information being displayed.

Conclusions

The Vessel Analysis add-on for ORS Visual (K100335) has similar intended uses as the substantially equivalent devices and has very similar technological characteristics to those devices. Minor technological differences do not raise any new questions regarding safety or effectiveness of the device. Thus, Vessel Analysis add-on for ORS Visual (K100335) is substantially equivalent to the commercially available devices (see section 12).

The Vessel Analysis add-on for the ORS Visual software (K100335) has been extensively tested on a variety of platforms by both members of the development and quality control team and by potential customers serving as beta testers. A hazard analysis has been conducted and the level of concern has been classified as moderate. The release version of the software will be required to pass all tests considered critical in terms of patient safety and demonstrate an overall acceptable performance for release as determined by the predefined release criteria.

As specified in the proposed labeling and indications of use, the devices do not support mammographic and compressed images for viewing. Therefore, since the devices do not use compression technique that can result in the loss of data, no measurement of the error of the compressed image relative to the original has been performed (see section 18).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Object Research Systems (ORS) Inc.
% Mr. Jeff D. Rongero
Senior Project Engineer
UL LLC
12 Laboratory Drive
Research Triangle, NC 27709

November 28, 2012

Re: K122429
Trade/Device Name: Vessel Analysis and Autoplaque for ORS Visual
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: November 9, 2012
Received: November 13, 2012

Dear Mr. Rongero:

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.

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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Michael D. O'Hara

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

4. INDICATIONS FOR USE

510(k) Number: Unknown

Device Name: Vessel Analysis for ORS Visual

Indications for Use:

Vessel Analysis is intended to provide an optimized non-invasive application to analyze vascular anatomy and pathology and aid in determining treatment paths from a set of Computed Tomography (CT) Angiographic images.

Vessel Analysis is a post processing application option for the ORS Visual (K100335) platform family of products and can be used in the analysis of 2D/3D CT Angiography images/data derived from DICOM 3.0 compliant CT scans for the purpose of cardiovascular and vascular disease assessment. This software is designed to support the physician in assessment of stenosis analysis, pre/post stent procedure and directional vessel tortuosity visualization.

Vessel Analysis automatic visualization tools provide the users with the capabilities to facilitate segmentation of bony structures for accurate identification of the vessels. Once vessels are visualized, tools are available for sizing the vessel, analyzing calcified and non-calcified plaque to determine the densities of plaque within a coronary artery, measure areas of abnormalities within a vessel.

The software is not intended to replace the skill and judgment of a qualified medical practitioner and should only be used by people who have been appropriately trained in the software's functions, capabilities and limitations. Users should be aware that certain views make use of interpolated data. This is data that is created by the software based on the original data set. Interpolated data may give the appearance of healthy tissue in situations where pathology that is near or smaller than the scanning resolution may be present.

ORS Visual software (K100335) and the Vessel Analysis add-on must be installed on a suitable commercial computer platform. It is the user's responsibility to ensure the monitor quality and ambient light conditions are consistent with the clinical applications. Typical users of Vessel Analysis and ORS Visual (K100335) are trained medical professionals, including but not limited to radiologists, clinicians, technologists, and others.

Prescription Use __X___	AND/OR	Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K122429 Concurrence of CDRH, Office of Device Evaluation (ODE)