DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

ULTRALINQ HEALTHCARE SOLUTIONS, INC.
% Ms. Rita King
CEO
MethodSense, Inc.
PO Box 110352
DURHAM NC 27709

July 17, 2015

Re: K143176
Trade/Device Name: UltraLinq
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: June 15, 2015
Received: June 17, 2015

Dear Ms. King:

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,

Robert A Ochs

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143176

Device Name
UltraLinq

Indications for Use *(Describe)*
UltraLinq is a software image management system intended to receive, process, review, display, and archive medical images and data from imaging modalities (e.g. Ultrasound (US), and Magnetic Resonance (MR)). Images and data can be stored, communicated and displayed across computer systems and mobile devices. UltraLinq is a single system that can run on a web-enabled computer, iPad and iPhone and may be interfaced with other PACS systems. Diagnosis is not performed by the software but by qualified Physicians. Typical users of this system are trained and qualified professionals, e.g. physicians, radiologists, nurses, medical technicians, and assistants.
UltraLinq is used to:

- share reports and studies with other UltraLinq users,
- review reports and studies,
- download and save reports and studies,
- send reports and studies to EMR and EHR systems, and
- route reports and studies to other UltraLinq users.

UltraLinq provides access to medical images on mobile devices for non-diagnostic viewing and referral purposes. The mobile device access functionality is used for patient management by the medical community in order to access and display patient data, medical reports, and medical images. Mobile devices are not intended to replace full diagnostic workstations and should be used only when there is no access to a workstation.

UltraLinq is also intended for non-invasive processing of already acquired echocardiographic images in order to detect, measure, and calculate the left ventricular wall for left ventricular function evaluation. This measurement, available on workstations only, can be used to assist the clinician in cardiac evaluation.

This device is not to be used for mammography.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

UltraLinq K143176

This 510(k) Summary is in conformance with 21CFR 807.92

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Chief Executive Officer

Date Prepared: June 15, 2015

Device Name and Classification

Trade Name: UltraLinq
Common Name: Picture Archiving Communications System (PACS)
Classification: Class II
Regulation Number: 892.2050 – Picture Archiving and Communications System (PACS)
Classification Panel: Radiology
Product Code: LLZ

Predicate Devices:

	Primary Predicate	**Secondary Predicate**
Trade Name	ASTRA	LVivo EF Software Application
Common Name	Picture Archiving Communications System	Picture Archiving Device
510(k) Submitter / Holder	Candelis, Inc.	DiACardio, Ltd.
510(k) Number	K111694	K130779
Regulation Number	892.2050	892.2050
Classification Panel	Radiology	Radiology
Product Code	LLZ	LLZ

Device Description and Intended Use

UltraLinq is a web-based software application that provides image processing and viewing tools and access to studies and reports from a web-enabled computer, iPad or iPhone.

UltraLinq is intended for use by a physician or other trained medical professionals to receive, process, review, display and archive medical images and data from imaging modalities. Diagnosis is not performed by the software but by qualified Physicians.

UltraLinq is also intended for non-invasive processing of already acquired echocardiographic images in order to detect, measure, and calculate the left ventricular wall for left ventricular function evaluation. This measurement, available on workstations only, can be used to assist the clinician in a cardiac evaluation.

UltraLinq conforms to the ACR/NEMA DICOM 3.0 standard for interoperability with other DICOM compliant systems.

Indications for Use

UltraLinq is a software image management system intended to receive, process, review, display, and archive medical images and data from imaging modalities (e.g. Ultrasound (US), and Magnetic Resonance (MR)). Images and data can be stored, communicated and displayed across computer systems and mobile devices. UltraLinq is a single system that can run on a web-enabled computer, iPad and iPhone and may be interfaced with other PACS systems. Diagnosis is not performed by the software but by qualified Physicians. Typical users of this system are trained and qualified professionals, e.g. physicians, radiologists, nurses, medical technicians, and assistants.

UltraLinq is used to:

- share reports and studies with other UltraLinq users,
- review reports and studies,
- download and save reports and studies,
- send reports and studies to EMR and EHR systems, and
- route reports and studies to other UltraLinq users.

UltraLinq provides access to medical images on mobile devices for non-diagnostic viewing and referral purposes.

The mobile device access functionality is used for patient management by the medical community in order to access and display patient data, medical reports, and medical images. Mobile devices are not intended to replace full diagnostic workstations and should be used only when there is no access to a workstation.

UltraLinq is also intended for non-invasive processing of already acquired echocardiographic images in order to detect, measure, and calculate the left ventricular wall for left ventricular

function evaluation. This measurement, available on workstations only, can be used to assist the clinician in cardiac evaluation.

This device is not to be used for mammography.

Substantial Equivalence

UltraLinq is substantially equivalent to predicate devices currently on the market. These devices are:

- ASTRA by Candelis, Inc – K111694 (primary predicate device)
- LVivo EF Software Application by DiACardio, Ltd – K130779 (secondary predicate device)

UltraLinq has the same intended use and indications for use as the predicate devices. The table below provides a detailed comparison of UltraLinq to the predicate devices.

Detailed Comparison of the Subject and Predicate Devices

Item	Subject Device UltraLinq	Primary Predicate Device ASTRA	Secondary Predicate Device LVivo EF Software Application	Comparison
Intended Use	UltraLinq is intended for use by a physician or other trained medical professionals to receive, process, review, display and archive medical images and data from imaging modalities. UltraLinq is also intended for non-invasive processing of already acquired echocardiographic images in order to detect, measure, and calculate the left ventricular wall for left ventricular function evaluation. This measurement, available on workstations only, can be used to assist the clinician in a cardiac evaluation. Diagnosis is not performed by the software but by qualified Physicians.	ASTRA is intended to be used by trained professionals, e.g. Physicians, radiologists, nurses, medical technicians, and assistants to receive, process, review, display, print and archive medical images and data from imaging modalities. Diagnosis is not performed by the software but by Radiologists, Clinicians or referring Physicians.	LVivo EF Software Application is intended for non-invasive processing of already acquired echocardiographic images in order to detect, measure, and calculate the left ventricular wall for left ventricular function evaluation. This measurement can be used to assist the clinician in a cardiac evaluation.	Identical to the LVivo EF Software Application. Equivalent to ASTRA with the exception that UltraLinq does not print images.
Indications for Use	UltraLinq is a software image management system intended to receive, process, review, display, and archive medical	ASTRA is software image management intended to receive, process, review, display, print and archive medical images and data	LVivo EF Software Application is intended for non-invasive processing of already acquired	Identical to LVivo EF Software Application Equivalent to ASTRA with the exception that

	images and data from imaging modalities (e.g. Ultrasound (US), and Magnetic Resonance (MR)). Images and data can be stored, communicated and displayed across computer systems and mobile devices. UltraLinq is a single system that can run on a web-enabled computer, iPad and iPhone and may be interfaced with other PACS systems. Diagnosis is not performed by the software but by qualified Physicians. Typical users of this system are trained and qualified professionals, e.g. physicians, radiologists, nurses, medical technicians, and assistants. UltraLinq is used to: • share reports and studies with other UltraLinq users, • review reports and studies, • download and save reports and studies, • send reports and studies to EMR and EHR systems, and • route reports and studies	from imaging modalities (e.g. CR and DR). Images and data can be stored, communicated, and displayed within the system or across computer systems. ASTRA is comprised with three configurations depending upon the requirements of the user and desired options: ASTRA PLUS, ASTRA Lite, and ASTRA Mobile. ASTRA runs on a PC workstation, iPad, or iPhone and may be interfaced with verified and validated image acquisition devices from Candelis or other PACS systems. Diagnosis is not performed by the software but by Radiologists, Clinicians or referring Physicians. Typical users of this system are trained professionals, e.g. physicians, radiologists, nurses, medical technicians, and assistants. ASTRA Plus is used to: share reports and studies with other ASTRA peers,	echocardiographic images in order to detect, measure, and calculate the left ventricular wall for left ventricular function evaluation. This measurement can be used to assist the clinician in a cardiac evaluation.	UltraLinq does not print images and is not to be used for mammography. Also, equivalent to ASTRA, UltraLinq provides three different interfaces and runs on iPad and iPhone but instead of 3 different configuration implementations as provided by ASTRA, UltraLinq is comprised of a single configuration.

	to other UltraLinq users. UltraLinq provides access to medical images on mobile devices for non-diagnostic viewing and referral purposes. The mobile device access functionality is used for patient management by the medical community in order to access and display patient data, medical reports, and medical images. Mobile devices are not intended to replace full diagnostic workstations and should be used only when there is no access to a workstation. UltraLinq is also intended for non-invasive processing of already acquired echocardiographic images in order to detect, measure, and calculate the left ventricular wall for left ventricular function evaluation. This measurement, available on workstation only, can be used to assist the clinician in cardiac evaluation. This device is not to be used for mammography.	review reports and studies, download and save reports, send reports to local EMR, HER, RIS, HIS or PACS systems (HL7 send), route studies to PACS, Workstations, or other ASTRA peers. ASTRA Lite is used to: share reports and studies with ASTRA peers, review reports and studies, download and save reports, send reports to local EMR, HER, RIS, HIS or PACS system s (HL7 send). ASTRA Mobile is used to: share reports with other ASTRA peers, review reports, download and save reports, send reports to local EMR, HER, HIS or PACS systems (HL7 send). Only pre-processed DICOM for presentation images can be interpreted by primary image diagnosis in mammography. Lossy compressed Mammographic images		

		and digitized film screen images may only be interpreted using and FDA approved monitor that offers at least 5 Megapixel resolution and meets other technical specifications reviewed and accepted by FDA.		
Internet Based Software	Yes	Yes	No	Equivalent to ASTRA
Receive, store, retrieve, process, review, and/or display Medical Images	Yes	Yes	Yes	Equivalent to ASTRA and LVivo EF Software Application
Receives DICOM images from Imaging modalities.	Yes	Yes	Yes	Equivalent to ASTRA and LVivo EF Software Application.
Cloud-based computing and storage for transfer and sharing of studies, images and reports	Yes	Yes	No	Equivalent to ASTRA.
Software operates on off-the-shelf hardware	Yes	Yes	Yes	Equivalent to ASTRA and LVivo EF Software Application
Image storage and archive server	Yes	Yes	No	Equivalent to ASTRA
Displays images on mobile devices	Yes	Yes	No	Equivalent to ASTRA
Conforms to DICOM Standard	Yes	Yes	Yes	Equivalent to ASTRA and LVivo EF Software

for interoperability with other DICOM compliant systems				Application
Routing of images	Yes	Yes	No	Equivalent to ASTRA
Transmits images using lossy compression	Yes	Yes	No	Equivalent to ASTRA
Stores images using lossy compression	Yes	Unknown	No	Equivalent to ASTRA
Automated calculation of Left Ventricular Wall Boundary from Echocardiographic Videos	Yes	No	Yes	Identical to LVivo EF Software Application.
Calculation of ejection fraction based on computer ventricular wall boundaries	Yes	No	Yes	Identical to LVivo EF Software Application.
Scaling (Zoom In/Out)	Yes	Yes	No	Equivalent to ASTRA
Adjusting the brightness level	Yes	Yes	No	Equivalent to ASTRA
Panning	Yes	Yes	No	Equivalent to ASTRA
Adjusting contrast level	Yes	Yes	No	Equivalent to ASTRA
Window- level function	Yes	Yes	No	Equivalent to ASTRA

Testing

UltraLinq Healthcare Solutions has conducted verification and validation on the UltraLinq software. Software validation has been satisfactorily completed and the software met its performance requirements and specifications. Software validation was completed according to "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (May 11, 2005) for a device of moderate concern. Software Risk Analysis, Software Requirements Specification, Software Design Specifications, Traceability Analysis, Software Development Environment Description, and Revision History were completed in accordance with the guidance documents.

Performance testing of UltraLinq was conducted to validate that the device conforms to the defined user needs and intended uses.

UltraLinq integrates with DiACardio's LVivo EF to provide automated Ejection Fraction (EF) calculation. UltraLinq integrates the LVivo EF algorithm without changes. A Clinical Study was performed and submitted by DiACardio on the LVivo EF Software Application 510(k) K130779.

Substantial Equivalence Conclusions

In conclusion, the intended use for the UltraLinq device is the same as that of the predicate devices. The comparison demonstrates UltraLinq has similar device functions and other technological characteristics, and testing shows these functions perform as intended. This demonstrates that UltraLinq is substantially equivalent to the predicate devices and assures that UltraLinq is as safe and effective as the predicate devices.

Conclusion

The 510(k) Pre-market Notification for UltraLinq contains adequate information and data to determine that UltraLinq is as safe and effective as the legally marketed predicate devices.