Client Outlook Inc.
Christie Eby
Director of Operations & Quality
103 Bauer Place, Suite #3
Waterloo, ON N2T 2V2
CANADA

February 6, 2018

Re: K172490
Trade/Device Name: eUnity
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving And Communications System
Regulatory Class: Class II
Product Code: LLZ
Dated: January 2, 2018
Received: January 4, 2018

Dear Christie Eby:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara For

Robert A. Ochs, Ph.D.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172490

Device Name
eUnity

Indications for Use *(Describe)*

eUnity is a software application that displays medical image data and associated clinical reports to aid in diagnosis for healthcare professionals. It performs operations relating to the transfer, storage, display, and measurement of image data.

eUnity allows users to perform image manipulations, including window/level, rotation, measurement and markup. eUnity provides 2D display, Multi-Planar Reformatting and 3D visualization of medical image data, and mobile access to images.

eUnity displays both lossless and lossy compressed images. For lossy images, the medical professional user must determine if the level of loss is acceptable for their purposes. Display monitors or mobile devices used for reading medical images for diagnostic purposes must comply with applicable regulatory approvals and with quality control requirements for their use and maintenance. For mobile diagnostic usage when a full workstation is not available.

Mobile usage for mammography is for reference and referral only.

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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"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."

This 510(k) summary is submitted in accordance with the requirements of 21 CFR Part 807.92(c)

Basis for the submission:	Client Outlook hereby submits this traditional 510(k) submission for eUnity software which is substantially equivalent to the FDA cleared previous version of eUnity Software (k161515)
Submitter:	Client Outlook Inc. 103 Bauer Place, Suite #3 Waterloo, Ontario Canada N2L 6B5
Date:	August 14, 2017
Establishment Registration:	3009601121
Contact:	Christie Eby, Director of Operations & Quality Tel: 519-342-3049 x206 Fax: 519-725-2351
Trade Name:	eUnity
Common Name:	Medical Image Processing Software
Classification:	Picture Archiving and Communications Software (PACS)
Product Code:	LLZ
Device Class:	Class II
Regulation #:	21 CFR 892.2050
Device Panel:	Radiology

Predicate Devices:

Trade Name	510 (k) Submitter/ Manufacturer	510 (k) number
eUnity	Client Outlook Inc.	K161515

Reference Predicate Devices:

Trade Name	510 (k) Submitter/ Manufacturer	510 (k) number
Resolution MD	Calgary Scientific	K161130
Vue Motion	Carestream	K151774

Device Description:

Client Outlook has developed eUnity to load, display and manipulate medical (DICOM) images within a web-browser without installing client software. eUnity is a server-based software solution that extends common web-browsers on the most popular operating systems into medical review stations; removing a technical barrier that had long been a key contributor to poor medical image access.

eUnity is an enterprise medical image viewer that provides access to full quality images from anywhere using nothing more than a standard web browser. Combined with a calibrated monitor, it can be used to make diagnostic decisions. Secure, fast, immediate access to information means less time spent

searching for specialized workstations and supports greater efficiency for care, greater collaboration, and faster turnaround times.

This device is the successor to eUnity predicate (K161515) and adds the following functionality: MIP/MPR/3D and Mobile Diagnostic Use.

The following devices are validated for use with eUnity for Mobile:
iPhone version 6 and higher versions, iPad Mini and higher versions, iPad pro and higher versions, Samsung Galaxy Note 5 and higher versions, and Samsung Galaxy Tab E and higher versions.

Intended Use:

Client Outlook's eUnity enables health professionals to access, manipulate and collaborate real-time over full quality medical images using any web-browser without installing client software. eUnity is a server-based solution that connects to any PACS and displays DICOM images within the hospital, securely from remote locations, or as an integrated part of an EHR or portal. eUnity offers diagnostic quality images with the performance of installed PACS viewing software.

Indications for Use:

eUnity is a software application that displays medical image data and associated clinical reports to aid in diagnosis for healthcare professionals. It performs operations relating to the transfer, storage, display, and measurement of image data.

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Mobile usage for mammography is for reference and referral only.

Patient Interaction:

eUnity is a software device that handles medical images. It does not contact the patient, nor control any life sustaining devices. Prior to any medical decisions, a licensed medical practitioner reviews the output, providing ample opportunity for competent human intervention for the interpretation of images and information being displayed.

Comparison to predicate devices CHART:

System, Image Processing, Radiological				
Category	**Client Outlook 'eUnity'**	**A)Predicate Client Outlook 'eUnity'**	**B)Calgary Scientific ResolutionMD Mobile**	**C)Carestream Vue Motion**
510K		K161515	K133508	K151774
Class	Class II	Class II	Class II	Class II
Intended Use – for full descriptions – see appendices				
Intended Use	Diagnostic Quality	Diagnostic Quality	Diagnostic Quality	Diagnostic Quality
User Install Requirements	Thin Client - no install, runs within browser	Thin Client - no install, runs within browser	Thin Client - no install, runs within browser	Thin Client - no install, runs within browser
Communications	DICOM, IHE, Non-DICOM	DICOM, IHE	DICOM, Non-DICOM	DICOM, Non-DICOM
Modalities	CR, CT, DX, ECG, MR, MG, NM, OP, PR, PT, RF, SC, SR, US, XA, VL	CR, CT, DX, ECG, MR, MG, NM, OP, PR, PT, RF, SC, SR, US, XA, VL	CT, MR, CR, DX, ES, KO, NM, OP, OT, PT, SC, US, XA, IO, XC, RTIMAGE, OPT, SR, RF	CR, DR, CT, MR, NM, ECG, US
Tools				
Window Level, Rotate/Pan/Zoom, Reset, Presets, Invert	yes	yes	yes	yes
Multi-Study viewing, Image printing, Report Printing, Image Export	yes	yes	yes	yes

Metadata display/hide	yes	yes	yes	yes
Orientation labels, Keyboard shortcuts,	yes	yes	yes	yes
Measurement tools, Annotation tools (Line, Arrow, Polygon, Freehand, Text)	yes	yes	yes	yes
Full-screen mode, Collaboration, Multimonitor, Linking Series, Revert to Original, Image Sharing, Triangulation, Image scrolling, Layouts, Linked scrolling, Reference lines, Image flip and rotate, Image measurements,	yes	yes	yes	yes
Grayscale softcopy presentation states (GSPS)	yes	yes	yes	yes
KIN	yes	yes	yes	yes
Mag lens	yes	yes	yes	yes
MIP/MPR/3D Features:				

Multi-Planar reformat (MPR)	yes	no	yes	yes
Maximum Intensity Projection (MPR)	yes	no	yes	yes
Oblique and double-oblique reformat, Triangulate, Rotate	yes	no	yes	yes
3D Volume, orientation widget, Opacity preset, Scalpel Tool, Bone Removal	yes	no	yes	yes
Mobile Specific Features:				
Mobile Luminance Check(test to be performed by user to determine lighting conditions prior to diagnosis)	yes	no	yes	yes
Security				
Data Encryption	HTTPS	HTTPS	HTTPS	HTTPS
Data Security	Stored on Server	Stored on Server	Stored on Server	Stored on Server
Access Control	Can either use built in access control or when launched from parent application can	Can either use built in access control or when launched from parent application can	Can either use built in access control or when launched from parent application	Can either use built in access control or when launched from parent application

	utilize its access control	utilize its access control	can utilize its access control	can utilize its access controly

Summary of Testing and conclusion

As required by the Risk Analysis, designated individuals performed all verification and validation activities and results demonstrated that the device meets its design requirements and intended use, and that it is safe and effective. Verification testing executed by multiple team members included functional, smoke and regression tests and was complimented by beta tests performed by Client Outlook partners and Validation in test systems at customer sites.

Additional Clinical Validation testing based on typical clinical workflows was performed by trained radiologists in comparison with an existing device and on several different hardware devices. Refer to the Validation Summaries in Section 12 for additional information. There was consensus among all the Radiologists that the same diagnosis would be made on the mobile device with eUnity as on the predicate device in various lighting conditions.

Conclusion:

The Intended use and technological characteristics of the Client Outlook eUnity software are substantially equivalent, in our opinion, to those of the predicate device and reference devices and do not pose any new issues of safety and effectiveness. The device and the predicates are post-processing and provide the same or similar essential features of visualization of radiological data on mobile devices.

The modified eUnity device offers the same functionality as the K161515 eUnity device with the addition of the Mobile enhanced capabilities and 3D viewing capabilities that are found in the Reference Predicate device.