International Medical Solutions, Inc.
℅ Mr. Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive, Suite 510k
SAINT PAUL MN 55114

October 29, 2020

Re: K203058
Trade/Device Name: CloudVue
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: October 7, 2020
Received: October 8, 2020

Dear Mr. Bom:

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. 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 located 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.

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) for

devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; 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 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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203058

Device Name
CloudVue

Indications for Use *(Describe)*
CloudVue is a software application that displays medical image data to aid in diagnosis for healthcare professionals. It performs operations relating to the transfer, storage, display, and measurement of image data.

CloudVue allows users to perform image manipulations, including window/level, rotation, measurement and markup.

CloudVue provides 2D display, Multi-Planar Reformatting and 3D visualization of medical image data, and mobile access to images.

CloudVue 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 only when a full workstation is not available.

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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IMS CloudVue 510(k) Summary

K203058

a. Submitter

International Medical Solutions Inc.
2425 Matheson Blvd E Suite 800
Mississauga, ON, L4W 5K4
Canada

Phone: 1-949-232-9298
Email: vcolaco@imstsvc.com

Contact Person: Vernon Colaço, General Manager
Date Prepared: August 27, 2020
Submission Date: September 2, 2020

b. Device

Subject Device Information	
Device Trade Name	CloudVue
Device Common Name	Medical Image Processing Software
Classification Name	Picture Archiving and Communications System
510(k) Number	K203058
Product Code	LLZ
Device Class	Class II
Regulation Number	21 CFR 892.2050
Device Panel	Radiology

c. Predicate Device

Predicate Device Information	
Device Trade Name	eUnity
Manufacturer	Client Outlook Inc.
510(k) Number	K172490

The predicate device has not been subject to a design-related recall.

d. Device Description

CloudVue is a software application that allows for the display of medical image data within a web browser without installing client software. Conceptually, the application comprises two components: the web viewer and the web server. The server is installed on any computer that meets the minimum system requirements and is configured to communicate with a DICOM archive. The server is capable of DICOM and DICOMweb communication, which allows the connected DICOM archive to exist on a physical server or in the cloud, giving institutions the flexibility to choose a system infrastructure that is best suited to their needs.

CloudVue provides fast and secure access to full-fidelity CR, CT, DX, HC, IVUS, MR, NM, OP, OPT, OT, PT, SC, US, and XA images using Chrome, Safari, Firefox, or Edge web browsers. With interactive features, such as: multi-study viewing, multi-monitor support, customized screen and tool layouts, annotation saving and loading, measurement drawing and calibration, reference lines, key images, multi-planar reformatting (MPR), MIP, VR rendering, and image link sharing, CloudVue is a feature-rich solution that informs diagnostic decision-making by healthcare professionals.

CloudVue also supports these same features across the following devices: Windows 10 and higher, macOS X and higher, iPad Pro 2nd generation and higher, and iPad Air 3 and higher. This level of portability allows healthcare professionals to access their medical image data anytime, anywhere.

The display is not part of the subject device, CloudVue, however, is an essential component of a fully-functional imaging system. The end user will view the medical images on the display monitor of their choice.

e. Indications for Use

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

CloudVue allows users to perform image manipulations, including window/level, rotation, measurement and markup.

CloudVue provides 2D display, Multi-Planar Reformatting and 3D visualization of medical image data, and mobile access to images.

CloudVue 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 only when a full workstation is not available.

Usage for mammography is for reference and referral only.

f. Comparison of Technological Characteristics with the Predicate Device

Characteristic	IMS CloudVue	Client Outlook eUnity
510(k) Number	K203058	K172490
Regulatory Class	Class II	Class II
Subject to Device Recall	No	No
Intended Use		
Indications for Use	CloudVue is a software application that displays medical image data to aid in diagnosis for healthcare professionals. It performs operations relating to the transfer, storage, display, and measurement of image data. CloudVue allows users to perform image manipulations, including window/level, rotation, measurement and markup. CloudVue provides 2D display, Multi-Planar Reformatting and 3D visualization of medical image data, and mobile access to images. CloudVue 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 only when a full workstation is not available. Usage for mammography is for reference and referral only.	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 only when a full workstation is not available. Mobile usage for mammography is for reference and referral only.
User Installation Requirements	Thin client – no install; runs within browser	Thin client – no install; runs within browser
Communications	DICOM, Non-DICOM	DICOM, Non-DICOM, IHE
Modalities	CR, CT, DX, HC, IVUS, MR, NM, OP, OPT, OT, PT, SC, US, XA	CR, CT, DX, MR, PT, SC, US, XA, ECG, MG, NM, OP, PR, RF, SR, VL
Tools		
Window Level/Rotate/Pan/Zoom/Reset, Presets, Invert, Revert to Original, Image Flip, Image Rotate	Yes	Yes
Multi-Study Viewing, Image Export, Image Sharing	Yes	Yes

Metadata Display/Hide	Yes	Yes
Orientation Labels, Keyboard Shortcuts	Yes	Yes
Measurements, Annotations	Yes	Yes
Full-Screen Mode, Multi-Monitor, Layouts	Yes	Yes
Linking Series, Image Scrolling, Linked Scrolling, Reference Lines	Yes	Yes
Grayscale Softcopy Presentation States (GSPS)	Yes	Yes
Key Images	Yes	Yes
Magnification Lens	Yes	Yes
MPR/MIP/3D Features		
Multi-Planar Reformat (MPR)	Yes	Yes
Oblique and Double Oblique Reformatting	Yes	Yes
Maximum Intensity Projection (MIP)	Yes	Yes
Volume Rendering (VR)	Yes	Yes
Opacity Presets	Yes	Yes
Scalpel Tool, Bone Removal	No	Yes
Mobile-Specific Features		
Mobile Luminance Check	Yes	Yes
sSecurity		
Data Encryption	HTTPS	HTTPS
Data Security	Stored on server	Stored on server
Access Control	Built-in access control or parent application access control	Built-in access control or parent application access control

g. Clinical Performance Data

No clinical testing was required to support safety and effectiveness of the subject device.

h. Summary of Testing

Verification and validation activities, driven by risk analysis guided by ISO 14971:2007, were conducted and documentation was provided. These activities included unit testing, integration testing, system testing, and benchmark testing. The recommended portable display devices were all tested for image quality and found to be adequate. All testing activities demonstrated that the device met all design requirements and intended use, and that it is both safe and effective.

i. Conclusion

In summary, the predicate device is medical image processing software that provides its users with the tools to display and manipulate medical DICOM images without altering the original image itself. The

predicate device is a zero-footprint, software-only medical device that aids in, but does not provide, a diagnosis. It also displays diagnostic quality images for both workstations and mobile platforms. These technological characteristics that comprise the predicate device are substantially similar to the subject device. Therefore, we conclude that the intended use and technological characteristics of CloudVue are substantially equivalent to those of the predicate device, and do not pose any new issues of safety or effectiveness.