Hinacom Software and Technology, Ltd.
% Yi Isabelle Sun
Executive VP
Suite B301, R&D Plaza, Tsinghua Science Park
Haidian District, Beijing 100084
CHINA

August 2, 2018

Re: K171977
Trade/Device Name: miPlatform medical imaging suite v3.0, (miPlatform v3.0)
miPlatform ZFP Viewer
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: June 20, 2018
Received: June 25, 2018

Dear Yi Sun:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

for
Robert 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)*
K171977

Device Name
miPlatform medical imaging suite v3.0 (miPlatform v3.0), miPlatform ZFP Viewer

Indications for Use *(Describe)*
miPlatform medical imaging suite v3.0 (miPlaftorm v3.0) is an upgrade of miPlatform medical imaging suite v2.0, previous cleared under K131424. miPlatform v3.0 is an internet-based image management system intended to be used by trained professionals, including but not limited to physicians, nurses and medical technicians. The system is a software package that is used with general purpose computing hardware to acquire, store, distribute, process and display images and associated patient data. The software supports and performs reviewing, communication and storage from the following modalities through DICOM 3.0 standard: CT, MR, NM, US, XA, PET, DX, CR/DR, RF, RT, MG, SC, VL, ES, OP, XC, PT, OT, as well as hospital/radiology information systems and any other information systems that support DICOM 3.0 standards. Non-radiology modalities are not for diagnostic use. For radiology modalities, only FDA cleared monitors shall be used to review images for diagnostic use.

miPlatform ZFP Viewer is offered as extension application to miPlatform medical imaging suite system. This software technology uses HTML5 which allows a browser-enabled device to run the software application, and thus requires no installation (zero foot print). The user is able to access patient images and study reports from a mobile device, such as iPad3, as well as personal computer using Microsoft Windows System, anywhere through a wireless and 3G, 4G network. miPlatform ZFP Viewer has a simple GUI for viewing and includes tools such as zoom, pan, windowing, basic measurement, and 3D visualization functions, including volume rendering and multi-planar reconstruction. Only FDA cleared monitors shall be used to review images for diagnostic use.

miPlatform ZFP Viewer provides wireless and portable access to medical images, in addition to standard intranet or internet access. This device is not intended to replace full workstations and should be used only when there is no access to a workstation. When used on a mobile device, the miPlatform ZFP Viewer is not for diagnostic use.

For primary interpretation and review of mammography images, only use display hardware that is specifically designed for and cleared by the FDA for mammography. MIP/MRP tools are not supported for mammography images for diagnostic use.

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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7. 510(k) Summary

7.1. Identification of Submitter

Submitter: Hinacom Software and Technology Ltd. Co.
Address: Suite B-301, R&D Plaza, Tsinghua Science Park,
Haidian District, Beijing, China 100084
Phone: +1-872-2391620
Fax: +86-10-62701652

Contact: Yi Isabelle Sun
Title: Executive VP
E-mail: yi@hinacom.com
Phone: +1-872-2391620
Fax: +86-10-6270-1652

Summary Date: 11/08/2017

7.2. Identification of Product

Trade name: miPlatform medical imaging suite v3.0 (miPlatform v3.0), miPlatform ZFP Viewer
Common/Usual Name: Picture Archiving and Communications System
Classification Name: System, Image Processing Radiological (21 C.F.R. 892.2050, LLZ)
Device Classification: Class II
Manufacturer: Hinacom Software and Technology, Ltd.

Primary predicate device:
Trade/Device Name: miPlatform Medical Imaging Suite
Common/Usual Name: Picture Archiving and Communications System
Classification Name: LLZ, Class II, 21 CFR 892.2050
510(k) Number: K131424

Secondary predicate device:
Trade Name: CARESTREAM Vue PACS v11.4 Vue Motion
Common/Usual Name: Picture Archiving and Communications System
Classification Name: LLZ, Class II, 21 CFR 892.2050
510(k) Number: K132824

7.3. Indication for Use

miPlatform medical imaging suite v3.0 (miPlatform v3.0) is an upgrade of miPlatform medical imaging suite v2.0, previous cleared under K131424. miPlatform v3.0 is an internet-based image management system intended to be used by trained professionals, including but not limited to physicians, nurses and medical technicians. The system is a software package that is used with general purpose computing hardware to acquire, store, distribute, process and display images and associated patient data. The software supports and performs reviewing, communication and storage from the following modalities through DICOM 3.0 standard: CT, MR, NM, US, XA, PET, DX, CR/DR, RF, RT, MG, SC, VL, ES, OP, XC, PT, OT, as well as hospital/radiology information systems and any other information systems that support DICOM 3.0 standards. Non-radiology modalities are not for diagnostic use. For radiology modalities, only FDA cleared monitors shall be used to review images for diagnostic use.

miPlatform ZFP Viewer is offered as extension application to miPlatform medical imaging suite system. This software technology uses HTML5 which allows a browser-enabled device to run the software application, and thus requires no installation (zero foot print). The user is able to access patient images and study reports from a mobile device, such as iPad3, as well as personal computer using Microsoft Windows System, anywhere through a wireless and 3G, 4G network. miPlatform ZFP Viewer has a simple GUI for viewing and includes tools such as zoom, pan, windowing, basic measurement, and 3D visualization functions, including volume rendering and multi-planar reconstruction. Only FDA cleared monitors shall be used to review images for diagnostic use.

miPlatform ZFP Viewer provides wireless and portable access to medical images, in addition to standard intranet or internet access. This device is not intended to replace full workstations and should be used only when there is no access to a workstation. When used on a mobile device, the miPlatform ZFP Viewer is not for diagnostic use.

For primary interpretation and review of mammography images, only use display hardware that is specifically designed for and cleared by the FDA for mammography. MIP/MRP tools are not supported for mammography images for diagnostic use.

7.4.Device description

miPlatform v3.0 and miPlatform ZFP Viewer is the extension application software of miPlatform medical imaging information system. User can achieve mobile office through the software which is installed in PC, smart mobile phone and other mobile terminals.

- Understanding and analyzing patient's information and medical image in real time.
- Processing, diagnosing and sharing images in real time. Note that when used on a mobile device, the miPlatform ZFP Viewer is not for diagnostic use.
- Support three-dimensional image viewing and processing.

- Support image analysis and real-time data synchronization exchange in real-time conference.

Detail description of functionalities and technical characteristics can be found in Section 7.6 of this document.

7.5. Software Development

Hinacom certifies that the miPlatform v3.0 and miPlatform ZFP Viewer software are designed, developed, tested and validated according to written procedures. These procedures identify individuals within the organization responsible for developing and approving product specifications, coding and testing, validation testing and field maintenance. The software developed for this product is used to provide diagnostic quality images and associated information to the intended users.

7.6. Identified technological characteristics with predicate device:

	Device being submitted for 510(k)	**Predicate device**	**Predicate device**
Device	**miPlatform Medical Imaging Suite v3.0, miPlatform ZFP Viewer**	**miPlatform Medical Imaging Suite v2.0**	**CARESTREAM Vue PACS v11.4 Vue Motion**
510(k) number	**K171977**	**K131424**	**K132824**
Manufacturer	**Hinacom Software and Technology, Ltd**	**Hinacom Software and Technology, Ltd**	**Carestream Health, Inc.**
Class	Class II	Class II	Class II
Product code	LLZ	LLZ	LLZ
Indication for Use	miPlatform medical imaging suite v3.0 (miPlatform v3.0) is an upgrade of miPlatform medical imaging suite v2.0, previous cleared under K131424. miPlatform v3.0 is an internet-based image management system intended to be used by trained professionals, including but not limited to	miPlatform is an internet-based image management system intended to be used by trained professionals, including but not limited to physicians, nurses and medical technicians. The system is a software package that is used with	The CarestreamVue PACS is an image management system whose intended use is to provide completely scalable local and wide area PACS solution for hospital and related

	physicians, nurses and medical technicians. The system is a software package that is used with general purpose computing hardware to acquire, store, distribute, process and display images and associated patient data. The software supports and performs reviewing, communication and storage from the following modalities through DICOM 3.0 standard: CT, MR, NM, US, XA, PET, DX, CR/DR, RF, RT, MG, SC, VL, ES, OP, XC, PT, OT, as well as hospital/radiology information systems and any other information systems that support DICOM 3.0 standards. Non-radiology modalities are not for diagnostic use. For radiology modalities, only FDA cleared monitors shall be used to review images for diagnostic use. miPlatform ZFP Viewer is offered as extension application to miPlatform medical imaging suite system. This software technology uses HTML5 which allows a browser-enabled device to run the software application, and thus requires no installation (zero foot print). The user is	general purpose computing hardware to acquire, store, distribute, process and display images and associated data. The software performs digital image processing, analysis, reviewing, communication and storage. miPlatform supports receiving, sending, printing, storing and displaying studies received from the following modality types via DICOM: CT, MR, NM, US, XA, PET, DX, DR, RF, RT, MG, SC, VL, as well as hospital/radiology information systems and any other information systems that support DICOM 3.0 standard. miPlatform also supports multidimensional image visualization, measurement and analysis tools, and reporting algorithms. The user interface is designed to follow typical clinical workflow patterns to process, review, validate/edit and analyze digital images. The software supports the	institutions/ sites which will archive, distribute, retrieve and display images and data from all hospital modalities and information systems. The system contains interactive tools in order to ease the process of analyzing and comparing three dimensional (3D) images. It is a single system that integrates review, dictation and reporting tools to create a productive work environment for the radiologists and physicians. The CarestreamVue motion software program is used for patient management by clinicians in order to access and display patient data, medical reports, and medical images for diagnosis from different modalities including CR, DR,

	able to access patient images and study reports from a mobile device, such as iPad3, as well as personal computer using Microsoft Windows System, anywhere through a wireless and 3G, 4G network. miPlatform ZFP Viewer has a simple GUI for viewing and includes tools such as zoom, pan, windowing, basic measurement, and 3D visualization functions, including volume rendering and multi-planar reconstruction. Only FDA cleared monitors shall be used to review images for diagnostic use. miPlatform ZFP Viewer provides wireless and portable access to medical images, addition to standard intranet or internet access. This device is not intended to replace full workstations and should be used only when there is no access to a workstation. When used on a mobile device, the miPlatform ZFP Viewer is not for diagnostic use. For primary interpretation and review of mammography images, only use display hardware that is specifically designed for and cleared by the FDA for	following image analysis options: Vessel Analysis is an option intended for determining the presence and extent of vascular obstructive disease by providing a non-invasive survey of a patient's coronary or peripheral arteries. Physicians can select any artery to view the following anatomical references: the highlighted vessel in 3D, two rotate-able curved MPR vessel views displayed at angles orthogonal to each other, and cross sections of the vessel. Physicians can manually measure the lumen width to obtain percentage stenosis calculations. In addition, clinicians can manually measure vessel length along the centerline in standard curved MPR views and examine Hounsfield unit or signal intensity statistics. Coronary Calcium Scoring is an option intended for cardiac scoring from CT image derived measurements, including non-invasive detection and	CT, MR, NM and US. Carestream Vue Motion provides wireless and portable access to medical images for remote reading or referral purposes from browsers including usage with validated mobile devices. This device is not intended to replace full workstations and should be used only when there is no access to a workstation. For primary interpretation and review of mammography images, only use display hardware that is specifically designed for and cleared by the FDA for mammography. .

	mammography. MIP/MRP tools are not supported for mammography images for diagnostic use.	quantification of atherosclerotic plaque. Physicians can use semi-automatic tools in Coronary Calcium Scoring to mark calcified lesions of coronary arteries, and automated computation of Agatston scoring will be performed and presented in a report. miPlatform supports a real-time image-based conference option with integrated audio/video capability. Multiple users may log into the system and participate in the conference from different locations via internet connection.	
Graphical UI	Yes	Yes	Yes
Window O.S. - Client	Yes	Yes	Yes
Image input DICOM 3.0	Yes	Yes	Yes
Images stored on remote server	Yes	Yes	Yes
Network Protocol: TCP-IP	Yes	Yes	Yes
Query, retrieve,	Yes	Yes	Yes

display, store and process digital medical images			
Display of patient data	Yes	Yes	Yes
Multi-Planar reconstruction(MPR)	Yes (Not supported for Mammography image)	Yes	Yes
View Image	Yes	Yes	Yes
Zoom in/out Image	Yes	Yes	Yes
Pan Image	Yes	Yes	Yes
Set Window Width/Level	Yes	Yes	Yes
Length Measurement	Yes	Yes	Yes
Angle Measurement	Yes	Yes	Yes
cine	Yes	Yes	Yes
Modalities	CT, MR, NM, US, XA, DX, RF, VL, CR/DR, ES, OP, XC, PT, OT, MG	CT, MR, NM, US, XA, PET, DX, DR, RF, RT, MG, SC, VL	CR,DR,CT,MR,NM,US
Remote view	Yes	Yes	Yes
Communication standard	DICOM, HL7	DICOM, HL7	DICOM, HL7
authorized users	Yes	Yes	Yes

Timeline	Yes	Yes	No
Scroll Through Images	Yes	Yes	No
Reset Image	Yes	Yes	No
Text Label	Yes	Yes	No
Text-Arrow Labels	Yes	Yes	No
Annotation	Yes	Yes	No
ROI(Region of Interest)	Yes	Yes	No
Inverse/Rotate/Flip	Yes	Yes	No
Magnifying Glass	Yes	Yes	No
Display Point by Point	Yes	Yes	No
Delete Annotation and Measurement	Yes	Yes	No
Show/Hide Patient Information	Yes	Yes	No
Technological differences between miPlatform v3.0 and miPlatform ZFP Viewer			
Mobile Device Support for Diagnostic Viewing	1. miPlatform v3.0: PC 2. miPlatform ZFP Viewer: PC, Only when used with FDA cleared monitors	PC	PC, Tablet Computer
Operation Platform	1. miPlatform v3.0: Recommended	CPU: Intel I5 3.1 or higher	iPad 2, iPhone 4S, Galaxy S3, and

	Hardware Configuration of miPlatform server: CPU: Intel Xeon Processor 2GHz or higher Memory: 4GB or higher Graphics: NVIDIA GeForce GTS 250 or higher Hard Disk: 1TB or higher NIC: 10/100/1000 Base TX Network environment: a local or wide area network; Network bandwidth 10M or higher. Operation system: Window SQL Server 2008 or 2012 **Note: Please only use FDA cleared display monitors and workstations to display Mammograms for diagnosis.** Recommended Hardware Configuration of miPlatform viewer ● CPU: Intel Core i3 or higher ● Memory: 2GB or higher ● Hard Drives: 100GB or higher ● Operation System: Windows 7 or Windows 10 ● Display Device: Use FDA cleared diagnostic display. Recommended diagnostic display with minimum resolution 1366x768; The highest resolution 1680x1050 or higher ● NIC: 10/100/1000 Base	Memory: 4GB or higher Hard Drives: 250GB or higher NIC: Gigabit Ethernet Card Operating system: Window XP or above Browser: MS Internet Explorer 7 or above.	Galaxy Note 10. 1 or newer Version with equal or better performance.

	TX ● Network environment: a local or wide area network; Network bandwidth greater than 2M ● HD Camera ● Headset 2. miPlatform ZFP Viewer: Recommended Hardware Configuration of miPlatform ZFP viewer ● Mobile Terminal: iPad3；(Not for Diagnostic Use) ● Network Environment: Wifi/4G/3G, network bandwidth 2M or higher. ● Operating System: iOS 8.0 PC: ● CPU: Intel Core i3 or higher ● Memory: 2GB or higher ● Hard Drives: 100GB or higher ● Operation System: Windows 7 or Windows 10 ● Display Device: Use FDA cleared diagnostic display. ● NIC: 10/100/1000 Base TX ● Network environment: a local or wide area network; Network bandwidth greater than 2M		

Maximum Intensity projection (MIP)	1. miPlatform v3.0: Yes 2. miPlatform ZFP Viewer: Not supported	Yes	Yes
HTML 5	1. miPlatform v3.0: No 2. miPlatform ZFP Viewer: Yes	No	Yes
IOS	1. miPlatform v3.0: No 2. miPlatform ZFP Viewer: Yes	No	Yes
Mammographic Use	1. miPlatform v3.0: Yes, with FDA cleared monitors. 2. miPlatform ZFP Viewer: Not for diagnostic use	Yes	No

Functions performed on image modalities including OP, XC, OT, ES are the same as on radiological images. These modalities are not for diagnostic use.

Technological Characteristics:
The miPlatform v3.0 and miPlatform ZFP Viewer has similar technological characteristics and is similar in overall design, principal of operation and configuration compared to the Predicate Devices.

Performance
Support of the substantial equivalence of the miPlatform v3.0 and miPlatform ZFP Viewer device was provided as a result of software validation, which confirms all features of the miPlatform v3.0 and miPlatform ZFP Viewer device were compliant with the software requirements.

Basis for Determination of Substantial Equivalence:
Upon reviewing and comparing intended use, design, principle of operation and overall technological characteristics, the miPlatform v3.0 and miPlatform ZFP Viewer, when used on PC, is determined by Hinacom Software and Technology, Ltd. to be substantially equivalent to existing legally marketed devices.
The difference is that when used on a mobile device, the miPlatform ZFP Viewer is not for diagnostic use, which is specified in the Indications for Use and the labeling.

Testing

miPlatform v3.0 and miPlatform ZFP Viewer are tested successfully with reference to its Software Requirements Specification, as well as design verification and validation documents and Traceability Matrix document. Verification, validation, and testing activities establish the performance, functionality, and reliability characteristics of the miPlatform v3.0 and miPlatform ZFP Viewer, which is found to be safe and effective and substantially equivalent to the currently-cleared predication devices.

Testing involved system level functionality test, segmentation accuracy test, measurement accuracy test, interfacing test, usability test, serviceability test, labeling test, as well as the test for risk mitigation method analyzed and implemented in the risk management process. In addition, we conducted the performance comparison testing on retrospective images to help demonstrate that the proposed device is substantially equivalent to the predicate devices.

Pass/Fail criteria were based on the requirements and intended use of the product. Test results showed that all tests successfully passed.

7.7.Determination of Substantial equivalence:

Summary of Non-Clinical Tests:

The miPlatform v3.0 and miPlatform ZFP Viewer and their components comply with the following voluntary standards: NEMA PS3.1-3.18(2008) Digital Imaging and Communication in Medicine (DICOM) Set.

The performance of the software is tested in accordance with Hinacom's design control procedures to demonstrate intended performance. Potential hazards are controlled via risk management processes and verification and validation testing. Instructions for use are provided to facilitate intended operation.

miPlatform v3.0 and miPlatform ZFP Viewer were designed in compliance with the following Process Standards:

- DICOM PS 3.2. Digital Imaging and Communications in Medicine – Conformance Standard

The following quality assurance measures were applied to the development of the device:

- Risk Analysis
- Requirements Reviews

- Design Reviews
- Performance testing (verification)
- Safety testing (verification)
- Final acceptance testing (validation)

7.8.Performance Data from nonclinical Testing:

Designated individuals performed all verification and validation activities and results demonstrated that the predetermined acceptance criteria were met. The system passed all testing criteria.

Extensive performance tests had been conducted regarding the technological characteristics aspects. All tests had been passed successfully.

Applicable Standards：

DICOM standard for image data format and communication

7.9.Safety and Effectiveness

General Safety and Effectiveness Concerns:

The device labeling contains instructions for use and any necessary cautions and warnings, to provide for safe and effective use of the device. The hardware components specified are all "off the shelf" computer components.

7.10. Comparison with Predicate Devices

miPlatform v3.0 and miPlatform ZFP Viewer are substantially equivalent to several software applications that display, visualize, analyze and measure images and regions of interest. The predicate devices are miPlatform Medical Imaging Suite (K131424) and CARESTREAM Vue PACS v11.4 Vue Motion (K132824) which have been classified under 21 CFR 892.2050 as Class II medical device.

miPlatform v3.0 and miPlatform ZFP Viewer, when used on PC, are substantially equivalent to the identified predicate devices. All of these devices offer the visualization techniques, measurement and analysis tools which can be applied for more effective and accurate display, interpretation, and communication.

miPlatform v3.0 and miPlatform ZFP Viewer, when used on PC, are similar in characteristics, materials, and features, and have similar technological features, intended use and indications for use as the predicates, and do not pose any new issue of safety and effectiveness.

7.11. Conclusions

In summary, HINACOM software and technology, Ltd. is of the opinion that miPlatform v3.0 and miPlatform ZFP Viewer, when used on PC, do not introduce any new potential safety risk, is as effective and performs as well as devices currently on the market, and thus concludes that miPlatform v3.0 and miPlatform ZFP Viewer software, when used on PC, are substantially equivalent to the predicate devices.