DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

BOX, Inc.
% Mr. Carl Alletto
Consultant
OTech, Inc.
8317 Belew Drive
MCKINNEY TX 75071

September 1, 2015

Re: K151957
Trade/Device Name: BOX DICOM Viewer
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: August 18, 2015
Received: August 25, 2015

Dear Mr. Alletto:

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.
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)*

K151957

Device Name
BOX DICOM Viewer™

Indications for Use *(Describe)*

The BOX DICOM Viewer™ is a software Teleradiology system used to receive DICOM images, scheduling information and textual reports, organize and store them in an internal format, and to make that information available across a network via web and customized user interfaces. The BOX DICOM Viewer™ is used by hospitals, imaging centers, radiologist reading practices.

Contraindications: The BOX DICOM Viewer™ is not intended for the acquisition of mammographic image data and is meant to be used by qualified medical personnel only who are qualified to create and diagnose radiological image data.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

Date Prepared:

June 16, 2015

Submitter's Information: 21 CFR 807.92(a)(1)

Mr. Crispen Maung, VP Compliance
BOX INc.
4440 El Camino Real
Los Altos, CA 94022 USA
Email: compliance@ box.com

Trade Name, Common Name and Classification: 21 CFR 807.92(a)(2)

Trade Name:	BOX DICOM Viewer™
Common Name:	Picture, archive and communications system
Classification Name:	System, Image Processing, Radiological
Product Code:	LLZ

Predicate Device: 21 CFR 807. 92(a)(3)

Device Classification Name	system, image processing, radiological[23]
510(k) Number	K132799
Device Name	CLARISO PACS
Applicant	CLARISO, INC.
Regulation Number	892.2050
Classification Product Code	LLZ
Date Received	09/06/2013
Decision Date	11/07/2013
Decision	substantially equivalent (SESE)
Regulation Medical Specialty	Radiology
510k Review Panel	Radiology
summary	summary
Type	Traditional
Reviewed by Third Party	No
Combination Product	No

Device Description: 21 CFR 807 92(a)(4)

The BOX DICOM Viewer™ is a software system to be used to view DICOM compliant studies, which are stored. The BOX DICOM Viewer™ is intended for professional use only as a viewing tool for medical image studies.

BOX Inc. has acquired Clariso Inc. which included Clariso PACS (K132799), and cleared on November 11, 2013. The full features and functions of Clariso have been imported to the BOX DICOM Viewer, which includes the CLARISO PACS Viewer technology and features;

- Grayscale Image Rendering
- RGB Image Rendering
- Localizer Lines
- Localizer Point
- Orientation Markers
- Distance Markers
- Study Data Overlays
- Stack Navigation Tool
- Window/Level Tool
- Zoom Tool
- Panning Tool
- Horizontal/Vertical Flip
- Clockwise/Counterclockwise Rotation
- Color Inversion
- Text Annotation
- Area Measurement Annotation
- Angle Measurement Annotation
- Cobb Angle Measurement Annotation

In addition, the BOX Inc. has;

- Added new styles, colors, fonts, and icons were added for "BOX" look-and-feel
- Added WebGL rendering optimizations,
- Added Hardware accelerated rendering
- Added support for high resolution Retina displays,
- Added keyboard shortcuts for all tools and all annotation types

The BOX DICOM VIEWER software allows for acquisition of images from DICOM devices and lets users view those images from their personal computers. A third party DICOM device sends to the Box DICOM Proxy listener, the files are then sent to the Upload Proxy, then to the DICOM processor where the DICOM header data is extracted. Finally, the BOX DICOM VIEWER will communicate with a database component to store all the information required for patients, users, studies and configuration settings.

Indications for Use: 21 CFR 807 92(a)(5)

The BOX DICOM Viewer™ is a software Teleradiology system used to receive DICOM images, scheduling information and textual reports, organize and store them in an internal format, and to make that information available across a network via web and customized user interfaces. The BOX DICOM Viewer™ is used by hospitals, imaging centers, radiologist reading practices.

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Technological Characteristics: 21 CFR 807 92(a)(6)

The BOX DICOM Viewer™ is a software application that handles and manipulates digital medical images. 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 and printed. In general, a PACS (Picture Archiving and Communication System) is a medical imaging technology which provides storage of, and convenient access to, images from multiple modalities. Electronic images and reports are transmitted digitally via the PACS; this eliminates the need to manually file, retrieve, or transport film jackets. The universal format for PACS image storage and transfer is DICOM 3.x (Digital Imaging and Communications in Medicine). Non-image data, such as scanned documents, may be incorporated using consumer industry standard formats like PDF (Portable Document Format), once encapsulated in DICOM. The new device and predicate devices are substantially equivalent in the areas of technical characteristics, general function, application, and intended use.

The new device does not raise any new potential safety risks and is equivalent in performance to the existing legally marketed devices. Both systems have been developed to replace traditional film handling in radiology. The 2 devices are substantially equivalent in the areas of design, architecture, general function, application, and intended use. The predicate device and the new device are compared below:

The following information compares the predicate device and new device. Any differences between the predicate and the new device has no impact on safety or efficacy of the new device and does not raise any new potential safety risks and is equivalent in performance to existing legally marketed devices.

Ref #	Functionality	Predicate: CLARISO PACS (K132799)	Subject Device: BOX DICOM Viewer	If different, Impact on Safety and or Efficacy
1	Web Browser Software	Google Chrome for all features. Microsoft Internet Explorer & Mozilla Firefox for features except the DICOM Viewer	Same as predicate	No differences between predicate and subject device.
2	Intended use	Acquiring, viewing, editing and storing radiographs and related patients images	Same as predicate	No difference
3	Intended user	Radiologist & qualified medical personnel	Same as predicate	No difference
4	Network	10/100/100 Ethernet	Same as predicate	No difference

Ref #	Functionality	Predicate: CLARISO PACS (K132799)	Subject Device: BOX DICOM Viewer	If different, Impact on Safety and or Efficacy
5	Monitor	Above 19inch monitor (Using 1280x1024)	Same as predicate	No difference
6	User interaction/input	Same, Using 1280x1024	Same as predicate	No difference
7	Import / export images	Yes	Same as predicate	No difference
8	Acquisition devices	CT, MR, US, PET	Same as predicate	No difference
9	Image organization	Patient ID, Name, study instance UID	Same as predicate	No difference
10	Image search available	Same	Same as predicate	No difference
11	Image storage	Yes	Same as predicate	No difference
12	Database software	MySQL	Same as predicate	No difference
13	Greyscale Image Rendering	Yes	Same as predicate	No difference
14	RGB Image Rendering	Yes	Same as predicate	No difference
15	Localizer Lines	Yes	Same as predicate	No difference
16	Localizer Point	Yes	Same as predicate	No difference
17	Orientation Markers	Yes	Same as predicate	No difference
18	Distance Markers	Yes	Same as predicate	No difference
19	Study Data Overlays	Yes	Same as predicate	No difference
20	Stack Navigation	Yes	Same as predicate	No difference
21	Window Level	Yes	Same as predicate	No difference
22	Zoom in on images	Yes	Same as predicate	No difference
23	Panning	Yes	Same as predicate	No difference
24	Horizontal/Vertical Flip	Yes	Same as predicate	No difference
25	Clockwise/Countercl ockwise rotate	Yes	Same as predicate	No difference
26	Invert image	Yes	Same as predicate	No difference

Ref #	Functionality	Predicate: CLARISO PACS (K132799)	Subject Device: BOX DICOM Viewer	If different, Impact on Safety and or Efficacy
27	Text Annotation	Yes	Same as predicate	No difference
28	Area measurement annotation	Yes	Same as predicate	No difference
29	Angle measurement annotation	Yes	Same as predicate	No difference
30	Cobb Angle Measurement Annotation	Yes	Same as predicate	No difference
31	Image annotation	Yes	Same as predicate	No difference
32	Security	Yes	Same as predicate	No difference
33	DICOM 3.0 conformance	Yes	Same as predicate	No difference
34	Worklist	Yes	Same as predicate	No difference
35	Thumbnail viewing	Yes, thumbnails on preview, small, medium and large	Same as predicate	No difference
36	Login	Yes	Same as predicate	No difference
37	Audit	Yes, a tool to view access logs in real time.	Same as predicate	No difference
38	User Interface text styles, colors, fonts, and icons.	CLARISO PACS styles	BOX Styles	Yes, there are differences, however these changes do not affect device functions and does not raise new potential safety risks. Therefore, it is our determination that there is “No impact on safety or efficacy”
39	WebGL rendering optimizations	No hardware acceleration.	Yes, Hardware acceleration is used.	Yes, there are differences. See item 39 in section 7.1.1.1 below.
40	Support for high resolution Retina displays	Pixelated display on high-DPI displays only (i.e., “Retina Displays”).	Full pixel density on all displays	Yes, there is a difference. The subject device will display the full pixel density of the saved image where the predicate device only did so if it was set to “Retina Display” mode. This difference actually aids the viewer to always see the image as captured by the modality. The difference

Ref #	Functionality	Predicate: CLARISO PACS (K132799)	Subject Device: BOX DICOM Viewer	If different, Impact on Safety and or Efficacy
				does not affect the device IFU and does not raise new potential safety risks. Therefore, it is our determination that there is "No impact on safety or efficacy"
41	keyboard shortcuts for all tools and all annotation types	Limited keyboard shortcut support.	Keyboard shortcuts allowed for tools and all annotation types.	Yes, there is a difference. In the predicate, it was not possible for the User to use the inherent functions of the operating system to create keyboard short cuts. In the subject device, keyboard shortcuts allowed for tools and all annotation types which may help the User view images.

DIFFERENCE FOR ITEM 39 EXPLAINED

Ref #	Functionality	Impact on Safety and or Efficacy
39	WebGL rendering optimizations	WebGL (Web Graphics Library) is a JavaScript API for rendering interactive 3D computer graphics and 2D graphics within any compatible web browser without the use of plug-ins. WebGL is integrated completely into all the web standards of Internet browsers, allowing GPU accelerated usage of physics and image processing and effects as part of the web page canvas. WebGL elements can be mixed with other HTML elements and composited with other parts of the page or page background. WebGL programs consist of control code written in JavaScript and shader code that is executed on a computer's Graphics Processing Unit (GPU). Google Chrome – WebGL has been enabled on all platforms that have a capable graphics card with updated drivers since version 9, released in February 2011. By default, Windows Chrome uses the ANGLE (Almost Native Graphics Layer Engine) renderer to translate OpenGL ES to Direct X 9.0c or 11.0, which have better driver support. On Linux and Mac OS X the default renderer is OpenGL however, it is also possible to force OpenGL as the renderer on Windows. In computing, hardware acceleration is the use of computer hardware to perform some functions faster than is possible in software running on a more general-purpose CPU. Examples of hardware acceleration include blitting acceleration functionality in graphics processing units (GPUs) and regular expression hardware acceleration for spam control in the server industry. Normally, processors are sequential, and instructions are executed one by one. Various techniques are used to improve performance; hardware acceleration is one of them. The main difference between hardware and software is concurrency, allowing hardware to be much faster than software. Hardware accelerators are designed for computationally intensive software code. Depending upon granularity, hardware acceleration can vary

Ref #	Functionality	Impact on Safety and or Efficacy
		from a small functional unit to a large functional block (like motion estimation in MPEG-2). The hardware that performs the acceleration, when in a separate unit from the CPU, is referred to as a hardware accelerator, or often more specifically as a 3D accelerator, cryptographic accelerator, etc. Those terms, however, are older and have been replaced with less descriptive terms like video card or network adapter. Yes, there are differences, between the predicate and the subject device for WebGL since the subject device uses hardware acceleration and the predicate does not. However this difference do not affect the device IFU and does not raise new potential safety risks. The device has been tested and has passed predetermined criteria and therefore, it is our determination that there is "No impact on safety or efficacy".

Nonclinical Testing:

The BOX DICOM Viewer™ system and configuration has been assessed and tested at BOX Inc. and has passed all pre-determined testing criteria. The Verification & Validation Test Plan was designed to evaluate input functions, output functions, and actions performed by the BOX DICOM Viewer™ software in each operational mode and followed the process documented in the Validation Test Plan.

Nonclinical testing results are provided in the 510(k). Validation testing indicated, that as required by the risk analysis, designated individuals performed all verification and validation activities and that the results demonstrated that the predetermined acceptance criteria were met. If the device is installed by BOX Inc., integration and installations verification tests are conducted against acceptance criteria prior to release to the client.

Conclusion: 21 CFR 807 92(b)(1)

The 510(k) Pre-Market Notification for the BOX DICOM Viewer™ contains adequate information, data, and nonclinical test results to enable FDA - CDRH to determine substantial equivalence to the predicate device.

The subject device will be manufactured in accordance with the voluntary standards listed in the enclosed voluntary standard survey. The subject and predicate devices are substantially equivalent in the areas of technical characteristics, general function, application, and intended use. The modification to the subject device does not raise any new potential safety risks and is equivalent in performance to existing legally marketed devices.

Nonclinical tests demonstrate that the device is as safe, as effective, and performs as well as the predicate device.

Therefore, the BOX DICOM Viewer™ is substantially equivalent to the predicate device.