August 13, 2018

DigitalCore Co., Ltd
% Esin Yesilalan
Senior Regulatory Scientist
Voisin Consulting, Inc.
222 Third St. Suite 3121
CAMBRIDGE MA 02142

Re: K181318
Trade/Device Name: Onis-Pacs
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: May 17, 2018
Received: May 18, 2018

Dear Esin Yesilalan:

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 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)*
K181318

Device Name
ONIS-PACS

Indications for Use *(Describe)*
ONIS-PACS is a software device intended to be used by healthcare personnel and intended for viewing, reviewing, performing measurements/quantifications and reporting of medical images and data acquired from DICOM compliant medical imaging systems. Images and data can be stored, communicated, processed and displayed within the system or across computer networks at distributed locations. Lossy images and digitized film images must not be used for primary diagnosis or interpretation.

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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510(k) SUMMARY

I. Submitter Information

Company Name:	DigitalCore Co.,ltd
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Contact Person:	Cedric Lemoigne, DigitalCore Director cedric@dgcore.co.jp +81-90-5335-8104 (Japan) | +33-7-68-58-52-25 (France)
Date the summary was prepared:	August 7, 2018

II. Device Identification

Trade Name:	ONIS-PACS
Common Name:	Picture Archiving and Communication System
Classification Name:	System, Image Processing, Radiological
Product Code:	LLZ
Regulation Number:	892.2050
Device Class:	Class II

III. Identification of Predicate Devices

Device Name	iQ-System PACS
Manufacturer	IMAGE Information Systems Ltd
510(k) Number	K062488
Regulatory Class	Class II
Common Name	Picture Archiving and Communication System
Clearance Date	Sep 19 2006

IV. Device Description

ONIS-PACS is a Picture Archiving Communication System (PACS) fully compliant with the DICOM version 3.0 Standard. It is suitable for storing, distributing, retrieving, visualizing, manipulating, performing measurements/quantifications and reporting various DICOM objects.

ONIS Viewer is a desktop application that makes it possible to visualize, manipulate and process medical images of many different modalities. Basic and advanced tools are provided for manipulating and processing images, including multi-planar reconstruction and 3D volume rendering. The software also includes a Local Server service running in the background that can send and receive DICOM images and can respond to DICOM queries. The ONIS Viewer and the Local Server applications must run on the same computer.

ONIS Remote is a desktop application identical to the ONIS Viewer, except that it runs without the Local Server. It must connect to a Site Server to retrieve the studies to be retrieved and processed.

WebONIS is an ActiveX component loaded into an HTML page that provides the same functionality as the ONIS Remote application. It can only be used with the Microsoft Internet Explorer browser. The browser must connect to a web server to load the ActiveX component, and the latter then connects directly to an ONIS Site Server or an ONIS Organization Server.

ONIS Site Server is a server application that supports the storage and retrieval of a wide range of DICOM Storage objects. It also supports the storage and retrieval of graphical annotations and reports when connected to ONIS client applications (ONIS Viewer, ONIS Remote, and WebONIS).

ONIS Organization Server is a server that provides a single access point to multiple Site Servers.

V. Indications for Use

ONIS-PACS is a software device intended to be used by healthcare personnel and intended for viewing, reviewing, performing measurements/quantifications and reporting of medical images and data acquired from DICOM compliant medical imaging systems. Images and data can be stored, communicated, processed and displayed within the system or across computer networks at distributed locations. Lossy images and digitized film images must not be used for primary diagnosis or interpretation.

VI. Comparison to Predicate Devices

The table below summarizes the comparison between the ONIS-PACS and the iQ-System.

Device Name	New Device	Predicate Device	Comparison
Manufacturer	DigitalCore	IMAGE Information Systems Ltd	-
510(k) Number	To be assigned	K062488	-
Regulatory Class	Class II	Class II	EQUIVALENT
Regulation Number	21 CFR 892.2050	21 CFR 892.2050	EQUIVALENT
Product Code	LLZ	LLZ	EQUIVALENT

Device Name	New Device	Predicate Device	Comparison
Common Name	Picture Archiving Communications System	Picture Archiving Communications System	EQUIVALENT
Clearance Date	To be assigned	Sep 19 2006	-
Indications for Use	ONIS-PACS is a software device intended to be used by healthcare personnel and intended for viewing, reviewing, performing measurements/quantifications and reporting of medical images and data acquired from DICOM compliant medical imaging systems. Images and data can be stored, communicated, processed and displayed within the system or across computer networks at distributed locations. Lossy images and digitized film images must not be used for primary diagnosis or interpretation.	iQ-System PACS is a software device intended for viewing of images acquired from CT, MR, CR, DR, US and other DICOM compliant medical imaging systems when installed on suitable commercial standard hardware. Images and data can be captured, stored, communicated, processed, and displayed within the system and or across computer networks at distributed locations. Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary diagnosis or image interpretation. It is the User's responsibility to ensure monitor quality, ambient light conditions, and image compression ratios are consistent with clinical application.	EQUIVALENT – Both devices are software only devices intended to allow clinicians to view and process DICOM images, and communicate results over a network. Both devices provide support for mammographic images, and both devices contra-indicate that lossy images should not be used for primary diagnosis nor interpretation.
Prescription device	YES	YES	EQUIVALENT
Environment of Use	Prescription device, intended for use in a healthcare setting	Prescription device, intended for use in a healthcare setting	EQUIVALENT
Technological characteristics			
System Architecture	Software only device, comprises workstation and web software, as well as server software.	Software only device, comprises workstation and web software, as well as server software.	EQUIVALENT
Operating System	Windows 7, 8, 10 Microsoft Windows 2008 Server Standard Microsoft Windows 2012 Server Standard	Windows 2000 / XP	EQUIVALENT – The subject device works on newer versions of the same Microsoft Windows Operating System

Device Name	New Device	Predicate Device	Comparison
Data Access and Communication	Accesses DICOM data on removable media (USB drive, optical disk), local and network drives, and also accesses DICOM data from DICOM server applications using DICOM communication protocols	Accesses DICOM data from portable media as well as through server applications using DICOM communication protocols	EQUIVALENT – Both device access data using Standard DICOM protocols
Image file import	YES	YES	EQUIVALENT
Patient CD/DVD import	YES	YES	EQUIVALENT
Export to a portable memory	YES, Export to memory stick, optical media	YES , Export to memory stick	EQUIVALENT
Image export to image file or AVI video file	YES	YES	EQUIVALENT
Mammography Display	YES	YES	EQUIVALENT
Image Visualization	Supports 2D, Mammography, Multi Planar Reconstruction (Axial, Sagittal, Coronal, Oblique, Double Oblique), Maximum Intensity Projection and Volume Rendered views	Supports mammography display, Orthogonal and Oblique Multi Planar Reconstruction, Maximum Intensity Projection, Surface Shaded Display and Volume Rendered views	EQUIVALENT – Both devices support standard image and volume rendering views
Support for Hanging Protocols	YES	YES	EQUIVALENT
Annotation Tools	Supports text, arrow, angle, line and other user drawn region of interest shapes	Support for standard annotation tools	EQUIVALENT – Both devices provide standard annotation tools
Measurement Tools	Supports distance and angle measurements, and pixel statistics for user drawn regions of interest	Supports advanced measurement tools including Region of Interest computations	EQUIVALENT – Both devices provide standard measurement tools
Image Manipulation Tools (Window width/level, Pan, Zoom, etc.)	Provides tools for window width/level, pan, zoom, rotate, color LUT, opacity table, image filters	Provides tools for window width/level, pan, zoom, rotate, image filters, volume cropping and clipping, and other volume rendering color, transparency and light setting options	EQUIVALENT – Both devices provide standard image manipulation functionality
Data Output	Supports export of images to various image formats, and printing of images and reports.	Supports export of secondary capture images to the local imagebox, filesystem or PACS	EQUIVALENT – Both devices support export of images to multiple destinations

Device Name	New Device	Predicate Device	Comparison
Review report	YES (HTML format)	YES (SR formats)	EQUIVALENT – Both devices support report generation functionality, though the specific report format may be different
Windows print	YES	YES	EQUIVALENT
JPEG lossy/lossless compression	YES	YES	EQUIVALENT
Edit patient demographics	YES	YES	EQUIVALENT – Both devices allow for edit of patient demographics. ONIS-PACS implements technical controls to ensure that only authorized users can make these modifications.
DICOM Query/ Retrieve, DICOM Print	YES	YES	EQUIVALENT

Both ONIS-PACS and the predicate device have similar technological characteristics, and any differences are only related to the specific software implementation.

VII. Performance Testing

Like the predicate device, ONIS-PACS is a software only medical device. The ONIS- PACS was determined to present a moderate level of concern per the FDA guidance, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 11, 2005". Software Validation and Verification testing was performed on the ONIS-PACS device to demonstrate safety and effectiveness.

VIII. Conclusion

The subject device has the same intended use as the predicate device, and differences in technological characteristics do not raise different questions of safety and effectiveness. On this basis, ONIS-PACS is substantially equivalent to the legally marketed predicate device.