IRM, Inc
℅ Kim Yun Ik
Quality Manager
4th-D, Myung-Woo Bldg. 169, Yeoksam-ro
Gangnam-gu, Seoul 06247
REPUBLIC OF KOREA

July 9, 2020

Re: K201296
Trade/Device Name: i-Rapha Solution
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: May 8, 2020
Received: May 15, 2020

Dear Kim Yun Ik:

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

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)*
K201296

Device Name
i-Rapha Solution

Indications for Use *(Describe)*
i-Rapha Solution is intended for use as a primary diagnostic and analysis tool for diagnostic images for hospitals, imaging centers, radiologists and any user who requires and is granted access to patient image, demographic.
i-Rapha View, a component of i-Rapha Solution, displays and manages diagnostic quality DICOM images.
Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using cleared monitors intended for mammography display.

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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510(k) Summary

K201296

[As required by 21 CFR 807.92]

1. Date Prepared [21 CFR 807.92(a)(a)]

May 8, 2020

2. Submitter's Information [21 CFR 807.92(a)(1)]

- Name of Manufacturer:	IRM Inc.
- Address:	4th-D, Myung-Woo Bldg, 169, Yeoksam-ro, Gangnam-gu, Seoul, 06247, Republic of Korea
- Contact Name:	Kim Yun Ik / Quality Manager of IRM Inc.
- Telephone No.:	+82-70-8230-6690
- Fax No.:	+82-70-8230-6693
- Email Address:	yikim@irm.kr

3. Trade Name, Regulation Name, Classification [21 CFR 807.92(a)(2)]

Trade Name	i-Rapha solution
Regulation Number	21 CFR 892.2050
Regulation Name	Picture archiving and communications system
Regulation Class	II
Product Code	LLZ
Product Code Name	System, Image Processing, Radiological

4. Identification of Predicate Device(s) [21 CFR 807.92(a)(3)]

- 510(k) Number:	K152977
- Applicant:	DICOM Grid, Inc.
- Regulation Name:	Picture archiving and communications system
- Product Code:	LLZ
- Device Class:	II
- Device Name:	DG PACS

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5. Description of the Device [21 CFR 807.92(a)(4)]

The i-Rapha solution is a professional DICOM web browser application that conforms HTML5 standards to receive, store, and view DICOM images; utilizable under any web browser that supports HTML 5 protocols (e.g. Chrome Browser). This web browser application supports various types of annotation for medical images interpretation.

The i-Rapha solution is a software device that does not contact the patient, nor does it control any life sustaining devices. The software does not provide any diagnostic assistance to the physician.

The i-Rapha solution allows displaying of images and image studies that may not in the location as the modality. With its Web features, it is possible to review and manipulate the images of the studies located in a remote server.

The i-Rapha View, a component of i-Rapha Solution, is an HTML5-based DICOM Viewer. The i-Rapha View can be used in any operating system because it can be executed by using a web browsers and especially Google Chrome that supports HTML5 regardless of the type of operating system.

Any diagnostic determination or treatment is solely determined by a physician and not the software. A physician, providing ample opportunity for competent human intervention, interprets images and information being displayed and printed.

The i-Rapha solution allows users to take full advantage of the radiographic images from various modalities in order to obtain invaluable mission critical diagnostic data and images.

The users can access their own diagnostic environment anywhere, anytime on PC.

6. Indications for Use [21 CFR 807.92(a)(5)]

i-Rapha Solution is intended for use as a primary diagnostic and analysis tool for diagnostic images for hospitals, imaging centers, radiologists and any user who requires and is granted access to patient image, demographic.

i-Rapha View, a component of i-Rapha Solution, displays and manages diagnostic quality DICOM images.

Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using cleared monitors intended for mammography display.

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7. Technological Characteristics

There are no significant differences in the technological characteristics of this device compared to the predicate device which adversely affect safety or effectiveness. The below table is summarized and compared with the technological characteristics between the i-Rapha solution and the predicate device:

	Proposed Device	Predicate Device #1	SE note
K Number	K201296	K152977	-
Model	i-Rapha Solution	DG PACS	-
Manufacturer	IRM Inc.	DICOM Grid, Inc.	-
Classification Name	System, Image Processing, Radiological	System, Image Processing, Radiological	Same
Regulatory Number	21 CFR 892.2050	21 CFR 892.2050	Same
Product Code	LLZ	LLZ	Same
Classification	II	II	Same
Indications for use	i-Rapha Solution is intended for use as a primary diagnostic and analysis tool for diagnostic images for hospitals, imaging centers, radiologists and any user who requires and is granted access to patient image, demographic. i-Rapha View, a component of i-Rapha Solution, displays and manages diagnostic quality DICOM images. Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using cleared monitors intended for mammography display.	DG PACS software is intended for use as a primary diagnostic and analysis tool for diagnostic images for hospitals, imaging centers, radiologists, reading practices and any user who requires and is granted access to patient image, demographic and report information. DG Viewer, a component of DG PACS, displays and manages diagnostic quality DICOM images. Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using cleared monitors intended for mammography display. Not intended for diagnostic use on mobile devices.	Same
Type of Use	Prescription Use	Prescription Use	Same
Component	Standalone software	Standalone software	Same
Web Standard	HTML5	HTML5	Same
Utilization of Standards	Digital Imaging and Communications in Medicine (DICOM) Joint Photographic Experts Group (JPEG) Society of Motion Picture and Television Engineers (SMPTE)	Digital Imaging and Communications in Medicine (DICOM) Joint Photographic Experts Group (JPEG) Society of Motion Picture and Television Engineers (SMPTE)	Same
Modalities supported on display	CR, DR, CT, US, MR, RF and other DICOM formats	CR, DR, CT, US, MR, RF and other DICOM formats	Same

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		Proposed Device	Predicate Device #1	SE note
Operating System (Web Browser)		Microsoft Internet Explorer 11 or Later**** Apple Safari Google Chrome Firefox	Microsoft Internet Explorer 9 or Later Apple Safari Google Chrome Firefox	Differences
Image Communication Standard		DICOM	DICOM	Same
Mobile Viewer	Mobile Phone	N/A*	Support	Differences
	Tablet	N/A*	Support	Differences
Feature/ Functionality				
User Authentication		Log-in Log-out	Log-in Log-out	Same
Worklist (Study List)		Search and display Study List Search Studies View Image Series List Save Search Options Import DICOM Export DICOM Study Management Image Preview**	Search and display Study List Search Studies View Image Series List Save Search Options Import DICOM Export DICOM Study Management Report*** Share Study***	Similar
DICOM Query/Retrieve		DICOM Q/R	DICOM Q/R	Same
Patient List		Display Patient List** Search Patient**	Unknown	Differences
Viewer		Image Display Viewer Layout function Grid function Image maximize function Related Study List Series Thumbnail Study Information display function Transformation Image Viewing function Window W/L Measurement Annotation Image Processing Image Reset Export Image	Image Display Viewer Layout function Grid function Image maximize function Related Study List Series Thumbnail Study Information display function Transformation Image Viewing function Window W/L Measurement Annotation Image Reset Export Image Image Processing*** Study Management*** Navigating*** Calibration*** Image Print*** Series Ordering Management***	Similar

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	Proposed Device	Predicate Device #1	SE note
		Modify Image*** Record*** Report***	
DICOM Storage SCP	DICOM Storage SCP (SDHServer)	DICOM Storage SCP (Ambra Gateway)	Same

* The subject device supports only PC Viewer. This is described in the User's Manual, so the user will be aware of this.

** There is additional functionality in the subject device. The added features and functions of the subject device are described in the user's manual, so the user will be aware of the functionality. The additional items do not change the Intended Use of the subject device. The differences do not raise any new potential safety risks and therefore, we believe there is no impact on safety or efficacy for the subject device.

*** There is no functionality in the subjective device. The functionality in the predicate device is not essential for safety and efficacy and therefore, we believe there is no impact on safety or efficacy for the subject device.

****Microsoft Internet Explorer 9, 10 are no longer supported by Microsoft. The differences indicated, do not raise any new potential safety risks and therefore, there is no impact on safety or efficacy for the subject device.

Non-Clinical Test Summary

i-Rapha solution contains MODERATE level of concern software. Software was designed and developed according to a software development process and was verified and validated.

Software information is provided in accordance with FDA guidance: the content of premarket submissions for software contained in medical devices, issued on May 11, 2005.

Clinical Test Summary:

No clinical studies were considered necessary and performed.

8. Determination of Substantial Equivalence [21 CFR 807.92(b)(1) and 807.92]

There are no significant differences between i-Rapha solution and the predicate device, K152977 that would adversely affect the use of the product. It is substantially equivalent to these devices in indications for use and technology characteristics

9. Conclusion [21 CFR 807.92(b)(3)]

The i-Rapha solution has similar intended use and technical characteristics to the predicate device. The differences in technological characteristics do not raise different questions of safety and effectiveness. In addition, performance testing conducted demonstrate that the subject devices are as safe and effective as the predicate. Therefore, the subject devices are substantially equivalent to the predicate.