DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 12, 2017

Imaging Dynamics Company Ltd.
% Ms. Nicole Wherry
Chief Quality Officer
#130, 5310-29th Street NE
Calgary, AB T1Y 7E5
CANADA

Re: K171169
Trade/Device Name: Aquarius 8600 1417TG and Aquarius 8600 1717TG
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: September 21, 2017
Received: September 25, 2017

Dear Ms. Wherry:

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,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171169

Device Name
Aquarius 8600 1417TG and Aquarius 8600 1717TG

Indications for Use *(Describe)*
Intended for use by a qualified/trained doctor or technologist on both adult and pediatric patients for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts on both adult and pediatric patients. Applications can be performed with patient sitting, standing or lying in the prone or supine positions. Not intended for mammography.

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

Date Prepared: October 03, 2017

1. Submitter 21 CFR 807.92(a)(1):

Imaging Dynamics Company, Ltd. (IDC)
#130, 3510-29th Street
N.E. Calgary, Alberta, Canada T1Y 7E5
Tel: 403.251.9939 Fax: 403.251.1771
Contact: Nicole Wherry

2. Identification of the Device 21 CFR 807.92(a)(2):

Trade Name:	Aquarius 8600 1417TG and Aquarius 8600 1717TG
Model Names:	1417TG and 1717TG
Common Name:	Flat Panel Detector
Classification Name:	Stationary X-Ray System
Product Code:	MQB
Regulation Number:	21 CFR 892.1680
Device Class:	Class II

3. Equivalent legally marketed devices 21 CFR 807.92(a)(3):

Predicate device:	K170202, Aquarius 8600 1417TC and Aquarius 8600 1717TC, IDC
Clearance Date:	February 22, 2017
Trade Name:	Aquarius 8600
Model Names:	1417TC and 1717TC
Common Name:	Flat Panel Detector
Classification Name:	Stationary X-Ray System
Product Code:	MQB
Regulation Number:	21 CFR 892.1680
Device Class:	Class II

510(K) Summary

Reference legally marketed devices

K122928, DIGITAL FLAT PANEL X-RAY DETECTOR 1417PGA

K122182, DIGITAL FLAT PLANEL X-RAY DETECTOR 1717SGC

The 510(k) for K122928 and K122182 was submitted by the original equipment manufacturer. Imaging Dynamics Company Ltd. maintains adequate information demonstrating our legal right to distribute the device.

4. Description of the Device 21 CFR 807.92(a)(4):

The Aquarius 8600 1717TG and Aquarius 8600 1417TG are digital flat panels, specifically termed solid state digital X-Ray detector. This technology couples a scintillator with an a-Si TFT sensor, and through integration with a radiographic imaging system, x-ray images can be captured and digitalized. The resulting RAW files are DICOM 3.0 compatible allowing image files to be processed by IDC Magellan software.

The Aquarius 8600 1717TG and the Aquarius 8600 1417TG represents a modification of our own predicate device cleared under K170202, Aquarius 8600 1717TC.

The Aquarius 8600 1717TG and Aquarius 8600 1417TG integrates the 510(k) cleared flat panel detectors (K122928 and K122182) with IDC Magellan software and workstation. There were no changes made to the cleared panels, workstation or software. All components were integrated and tested to make the Aquarius 8600 1717TG and Aquarius 8600 1417TG medical devices.

The Aquarius 8600 will be marketed in two additional possible configurations:

Aquarius 8600 1717TG (tethered, 17 x 17 inch flat panel as a retrofit package with Magellan software).

Aquarius 8600 1417TG (tethered, 14 x 17 inch flat panel as a retrofit package with Magellan software).

510(K) Summary

5. Indications for Use (intended use) 21 CFR 807.92(a)(5):

Intended for use by a qualified/trained doctor or technologist on both adult and pediatric patients for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts on both adult and pediatric patients. Applications can be performed with patient sitting, standing or lying in the prone or supine positions. Not intended for mammography.

The intended use for the Aquarius 8600 1417TG and Aquarius 8600 1717TG (subject devices) has not changed from the intended use of the predicate device, Aquarius 8600 1717TC.

6. Technological Characteristics Summary: Predicate and proposed devices comparison 21 CFR 807.92(a)(6):

The proposed Aquarius 8600 1417TG and Aquarius 8600 1717TG devices described in this 510(k) have similar technological characteristics and the same indications for use as the predicate device, Aquarius 8600 models 1717TC. A summary table comparing the technological properties of the proposed devices to the predicate device has been provided in Table 1.

510(K) Summary

Table 1: Comparison of the Aquarius 8600 1717TG and Aquarius 8600 1417TG, with the Aquarius 8600 1717TC Predicate device

Characteristic	Proposed Imaging Dynamics Company Ltd. Aquarius 8600 1717TG	Proposed Imaging Dynamics Company Ltd. Aquarius 8600 1417TG	Predicate Imaging Dynamics Company Ltd. Aquarius 8600 1717TC
Feature			
510(k) number	K171169	K171169	K170202
Intended Use	Aquarius 8600 1717TG Digital Flat Panel X-Ray Detector is indicated for digital imaging solutions designed for general radiographic systems for human anatomy. It is intended to replace film or screen based radiographic systems in all general purpose diagnostic procedures. Not to be used for mammography.	Aquarius 8600 1417TG Digital Flat Panel X-Ray Detector is indicated for digital imaging solutions designed for general radiographic systems for human anatomy. It is intended to replace film or screen based radiographic systems in all general purpose diagnostic procedures. Not to be used for mammography.	Aquarius 8600 1717TC Digital Flat Panel X-Ray Detector is indicated for digital imaging solutions designed for general radiographic systems for human anatomy. It is intended to replace film or screen based radiographic systems in all general purpose diagnostic procedures. Not to be used for mammography
Detector Type	Amorphous Silicon, TFT	Amorphous Silicon, TFT	Amorphous Silicon, TFT
Scintillator	Gd_2O_2S:Tb	Gd_2O_2S:Tb	CsI:Tl
Imaging Area	17x17 inches	14x17 inches	17x17 inches
Pixel Matrix	3328 x 3328	2816 x 3328	3328 x 3328
Pixel Pitch	127 µm	127 µm	127 µm

Resolution	3.9 lp/mm	3.9 lp/mm	3.9 lp/mm
A/D Conversion	14/16 bit	14/16 bit	14 bit
Preview Time	≤ 2 seconds	≤ 2 seconds	≤ 2 seconds
Data Output	RAW *the RAW files are convertible into DICOM 3.0 by console software.	RAW *the RAW files are convertible into DICOM 3.0 by console software.	RAW *the RAW files are convertible into DICOM 3.0 by console software.
Dimensions	460 x 460 x 15.5 mm	384 x 460 x 15 mm	460 x 460 x 15.5 mm
Weight	4 kg	3.1 kg	4 kg
Application	General Radiology system or Portable system Available with upright stand, table, universal stand.	General Radiology system or Portable system Available with upright stand, table, universal stand.	General Radiology system or Portable system Available with upright stand, table, universal stand.
Added Optional Components	-	-	-

510(K) Summary

***** Compliance to NEMA PS 3.1-3.20 "Digital Imaging and Communications in Medicine (DICOM) Set

Key Technology Differences:

A. The only difference between the predicate device and the subject devices is the use of a variant scintillator. The proposed Aquarius 8600 1717TG and Aquarius 8600 1417TG subject device use Gadox scintillators whereas the predicate device uses Cesium Iodide scintillators.

Risk management activities are based on ISO 14971:2007 "Medical Devices – Application of Risk Management to Medical Devices". As identified in the IDC FMEA Risk Assessment, there are no differences in risk based on this change.

The scintillator differences between the predicate device and the proposed Aquarius 8600 1717TG and Aquarius 8600 1417TG devices does not affect device performance.

B. Software: IDC Magellan 3 software was integrated for use on the proposed Aquarius 8600 1717TG and Aquarius 8600 1417TG flat panel medical devices. The operating systems for the proposed Aquarius 8600 1717TG and Aquarius 8600 14147TG flat panels are identical to the predicate Aquarius 8600 1717TC model. IDC will supply the workstation and software with the medical devices proposed in this 510(k) application.

No changes were made to the previously cleared 1717SGC and 1417PGA detectors and associated firmware for the proposed Aquarius 8600 1717TG medical device.

No changes were made to the IDC Magellan 3 software for integration with the previously cleared 1717SCC and 1417PCA flat panels for the proposed Aquarius 8600 1717TG and Aquarius 8600 1417TG medical devices. As regular software maintenance was performed, full system level verification, validation and regression testing was performed.

No changes have been made to the IDC Magellan 3 software for integration with potential wireless technology. The FDA will be notified if changes will be required for wireless technology, at which time a separate premarket application will be submitted.

510(K) Summary

IDC Recommended Generator Specifications.

Exposure is controlled manually by the user through a hand-held trigger. Recommended generator specifications are provided to the user and identified below. If additional generator compatibility information is required customers will be notified to contact the Imaging Dynamics Help Desk.

Generator	Property	Power Requirement
40 kW CMP 200 DR X-ray generator	Line Voltage	208 VAC – 5% to 230 VAC + 10%, 1 phase 208 VAC – 5% to 230 VAC + 10%, 3 phase 400 VAC ± 10%, 3 phase 480 VAC ± 10%, 3 phase
	Line Frequency	50/60 Hz
	Momentary Current	275 Amps at 208 VAC (1 phase) 154 Amps/phase at 208 VAC (3 phase) 250 Amps at 230 VAC (1 phase) 139 Amps/phase at 230 VAC (3 phase) 80 Amps/phase at 400 VAC 65 Amps/phase at 480 VAC
	Nominal Current	≤ 5 Amps
	Momentary Power Consumption	55 kVA
50 kW CMP 200 DR X-ray generator	Line Voltage	208 VAC – 5% to 230 VAC + 10%, 3 phase 400 VAC ± 10%, 3 phase 480 VAC ± 10%, 3 phase
	Line Frequency	50/60 Hz
	Momentary Current	192 Amps/phase at 208 VAC 174 Amps/phase at 230 VAC 100 Amps/phase at 400 VAC 80 Amps/phase at 480 VAC
	Nominal Current	≤ 5 Amps
	Momentary Power Consumption	65 kVA
65 kW CMP 200 DR X-ray generator	Line Voltage	400 VAC ± 10%, 3 phase 480 VAC ± 10%, 3 phase
	Line Frequency	50/60 Hz
	Momentary Current	125 Amps/phase at 400 VAC 105 Amps/phase at 480 VAC
	Nominal Current	≤ 5 Amps
	Momentary Power Consumption	85 kVA

510(K) Summary

7. Summary of Safety and Performance Testing 21 CFR 807.92(b)

Non-Clinical Test Summary:

The results of the non-clinical studies demonstrate the Aquarius 8600 1717TG and Aquarius 8600 1417TG are substantially equivalent to the predicate device, Aquarius 8600 1717TC. The tests and corresponding results are summarized below:

A. Comparison of the Detective Quantum Efficiency (DQE), Modulation Transfer Function (MTF) and Noise Power Spectrum (NPS).

Detective Quantum Efficiency Comparison:

A comparison of measured DQE curves show that the proposed Aquarius 8600 1717TG and Aquarius 8600 1417TG devices have slightly reduced DQE performance at all spatial frequencies than the predicate device, the difference increasing as the spatial frequency increases.

	Aquarius 8600 1417TG Aquarius 8600 1717TG	**Aquarius 8600 1717TC**
DQE (0)	0.446	0.684

Modulation Transfer Function:

A comparison of measured MTF curves show that the Aquarius 8600 1717TG and Aquarius 8600 1417TG flat panels show similar but slightly improved response to the predicate device. Values tested below 1 lp/mm and above 3.5 lp/mm have been omitted from this summary. Values are an average of 4 measurements taken from 2.7uGy to 26.83uGy for the Aquarius 8600 1417TG panel and 1.7uGy to 10.1uGy for the Aquarius 8600 1717TG panel. The Complete MTF values and linearity graphs can be found in section 3 (subsection 3 to 5) of the associate SSXI Non-Clinical Report.

Spatial Frequency	**MTF Value**		
	Aquarius 8600 1417TG	**Aquarius 8600 1717TG**	**Aquarius 8600 1717TC**
1 lp/mm	0.596	0.585	0.502
2 lp/mm	0.290	0.283	0.230
3 lp/mm	0.142	0.144	0.104
3.5 lp/mm	0.095	0.103	0.083

510(K) Summary

Noise Power Spectrum:

A comparison of measured NPS curves show that the Aquarius 8600 1717TG and Aquarius 8600 1417TG flat panels have a similar noise performance profile at spatial frequencies as the predicate device.

Spatial Frequency	NPS Value	
	Aquarius 8600 1417TG Aquarius 8600 1717TG	**Aquarius 8600 1717TC**
0 lp/mm	8.56	8.10
1 lp/mm	4.21	3.20
2 lp/mm	1.43	1.20
3 lp/mm	0.64	0.60
3.5 lp/mm	0.52	0.55

B. Environmental, electrical, mechanical safety, and performance testing was completed for the Aquarius 8600 1717TG and Aquarius 8600 1417TG, and all testing passed, based on IEC 60601-1 Medical Electrical Equipment – Part I General Requirements for Basic Safety and Essential Performance, 3rd edition + CORR. 1:2006 + CORR. 2:2007 + A1:2012. EMC testing was completed based on IEC 60601-1-2:2007.

C. "Guidance For The Submission of 510(K)s For Solid State X-Ray Imaging Devices" was utilized for clinical and non-clinical considerations. Results indicate the Aquarius 8600 1717TG and Aquarius 8600 1417TG are substantially equivalent to the IDC Aquarius 8600 1717TC predicate device.

D. IDC software has a documented lifecycle based on IEC 62304 Edition1.1:2015 "Medical Device Software – Software Lifecycle Processes". IDC software design and requirements specifications, classification of hazards, and full verification, validation, and regression testing is based on the FDA documents "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" and "General Principles of Software Validation; Final Guidance for Industry and FDA Staff".

E. Laboratory images using phantoms were acquired with the proposed IDC Aquarius 8600 1717TG subject device and compared to images acquired with the IDC Aquarius 8600 1717TC predicate device. A Radiological Technologist certified in the United States of America and Canada has reviewed the images (included in this submission) and determined the subject device produce images that are diagnostically similar, and slightly superior, to the predicate device.

F. **Clinical Test Summary:**

No clinical testing was performed for this special 510(k) submission.

8. Conclusion:

The Aquarius 8600 1717TG and Aquarius 8600 1417TG medical devices have identical indications for use, and similar technological characteristics as the Aquarius 8600 1717TC predicate device.

The flat panel components for the Aquarius 8600 1717TG and Aquarius 8600 1417TG are identical to the flat panels listed as reference devices (cleared separately in K122182 and K122928), and employs the same software as the IDC Aquarius 8600 1717TC predicate device.

The proposed Aquarius 8600 1717TG and Aquarius 8600 1417TG Flat Panels conform to US Performance Standards and are UL listed to US Standards for safety for medical devices.

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, it is the opinion of IDC that the Aquarius 8600 1717TG and Aquarius 8600 1417TG are substantially equivalent in comparison with the IDC Aquarius 8600 1717TC predicate device as described herein.