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

February 22, 2017

Imaging Dynamics Company Ltd.
% Ms. Nicole Wherry
Chief Quality Officer
130, 3510 29th Street NE
Calgary, Alberta T1Y 7E5
CANADA

Re: K170202
Trade/Device Name: Aquarius 8600
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: December 14, 2016
Received: January 23, 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)*

K170202

Device Name
Aquarius 8600

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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Exhibit # 8: 510(K) Summary

510(K) Summary, Special 510(k) K

Date Prepared: 21 February, 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
Model Names:	1717TC and 1417TC
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:	K070079, X3C Digital Radiographic Detector, IDC
Trade Name:	X3C Digital Radiographic Detector
Model Names:	X3C
Common Name:	Digital Imaging X-Ray Detector
Classification Name:	Stationary X-Ray System
Product Code:	MQB
Regulation Number:	21 CFR 892.1680
Device Class:	Class II

Reference legally marketed devices

K111098, InnovaXion FP, IDC (Imaging Dynamics Company)

K122173, Digital Flat Panel X-Ray Detector, 1717SCC

K122919, Digital Flat Panel X-Ray Detector, 1417PCA

The 510(k) for K122173 and K122919 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 1717TC and 1417TC 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 1717TC and 1417TC represents a modification of our own predicate device cleared under K070079, X3C Digital Radiographic Detector.

The Aquarius 8600 1717TC and 1417TC integrates the 510(k) cleared flat panel detectors (K122173 and K122919) 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 1717TC and 1417TC medical devices.

Note: The integration of the 1717TC and 1417TC flat panel detectors and Magellan software with the workstation is exactly the same integration as the IDC marketed flat panel, InnovaXion FP, with Magellan software and workstation cleared under K111098.

The Aquarius 8600 will be marketed in two possible configurations:

Aquarius 8600 1717TC (tethered, 17 x 17 inch flat panel as a retrofit package with Magellan software) referred to as “1717TC” throughout the rest of this document

Aquarius 8600 1417TC (tethered, 14 x 17 inch flat panel as a retrofit package with Magellan software) referred to as “1417TC” throughout the rest of this document.

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.

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

The proposed 1717TC and 1417TC devices described in this 510(k) have similar technological characteristics and the same indications for use as the predicate device, X3C Digital Radiographic Detector. A summary table comparing the technological properties of the proposed devices to the predicate device has been provided in Table 1.

Table 1: Comparison of the Aquarius 8600, models 1717TC and 1417TC with the X3C Predicate

Characteristic	**Proposed IDC Aquarius 8600, model 1717TC**	**Proposed IDC Aquarius 8600, model 1417TC**	**Predicate IDC X3C**
Feature			
IDC 510(k) number	*K170202*	*K170202*	K070079
Reference Device 510(k) #	K122173	K122919	K070079

Intended Use	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.	1417TC 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.	X3C 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	D50 Dalsa /K70 Kodak Camera
Scintillator	CsI:Tl	CsI:Tl	CsI:Tl
Imaging Area	17x17 inches	14x17 inches	17x17 inches
Pixel Matrix	3328 x 3328	2816 x 3328	3000 x 3000
Pixel Pitch	127 µm	127 µm	144 µm
Resolution	3.9 lp/mm	3.9 lp/mm	3.4 lp/mm
A/D Conversion	14/16 bit	14/16 bit	14 bit
Preview Time	≤ 2 seconds	≤ 2 seconds	≤ 6 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.
Firmware	The Firmware provided with the flat panel will be utilized in this medical device without modification and has the same functionality as the IDC X3C Firmware.	The Firmware provided with the flat panel will be utilized in this medical device without modification and has the same functionality as the IDC X3C Firmware.	IDC Firmware. Has the same functionality as the 1717TC and 1417TC flat panel Firmware.
Software	IDC Magellan 3 is a software program that uses the latest digital imaging and processing techniques to acquire, store, retrieve, transmit, and print medical images for immediate review and disposition. DICOM 3.0 compliant.	IDC Magellan 3 is a software program that uses the latest digital imaging and processing techniques to acquire, store, retrieve, transmit, and print medical images for immediate review and disposition. DICOM 3.0 compliant.	IDC Magellan 3 is a software program that uses the latest digital imaging and processing techniques to acquire, store, retrieve, transmit, and print medical images for immediate review and disposition. DICOM 3.0 compliant.
Dimensions	460 x 460 x 15.5 mm	384 x 460 x 15 mm	943 x 540 x 388 mm

Weight	4 kg	3.1 kg	75 kg
Application	General Radiology system Use with upright stand, table, universal stand.	General Radiology system Use with upright stand, table, universal stand.	General Radiology system Use with upright stand, table, universal stand
Storage and Transportation	Storage and transportation Conditions: Temperature -10 to +50°C Humidity 10 to 80%	Storage and transportation Conditions: Temperature -10 to +50°C Humidity 10 to 80%	Storage and transportation Conditions: Temperature -40 to +40°C Humidity 0 to 70%

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

Key Technology Differences:

A. Dimensions & weight: the predicate IDC X3C is a larger and heavier imaging detector than the proposed 1717TC and 1417TC flat panels.

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, the decrease in size and weight of the proposed 1717TC and 1417TC has led to decreased safety risks when compared to the predicate IDC X3C device. The Risk Assessment identified the predicate IDC X3C to hold a higher risk for injury during potential safety incidents than those of the proposed 1717TC and 1417TC flat panels based on the size and weight of each medical device.

The size and weight differences between the predicate device and the proposed 1717TC and 1417TC devices does not affect device performance.

B. Software: IDC Magellan 3 software was integrated for use on the proposed 1717TC and 1417TC flat panel medical devices. The operating systems for the proposed 1717TC and 14147TC flat panels are identical to the predicate X3C detector. 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 1717SCC and 1417PCA detectors and associated firmware for the proposed 1717TC and 1417TC medical devices.

No changes were made to the IDC Magellan 3 software for integration with the previously cleared 1717SCC and 1417PCA flat panels for the proposed 1717TC and 1417TC 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.

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

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 1717TC and 1417TC are substantially equivalent to the predicate device, X3C Digital Radiographic Detector. 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 1717TC and 1417TC flat panels has similar DQE performance at all spatial frequencies to the predicate IDC X3C detector. The 1717TC and 1417TC flat panels have a reduced pixel pitch and greater pixel count.

	1717TC and 1417TC	**X3C Detector**
DQE (0)	0.684	0.641

Modulation Transfer Function:

A comparison of measured MTF curves show that the 1717TC and 1417TC flat panels have the same or better resolution performance than the predicate IDC X3C detector at all spatial frequencies.

Spatial Frequency	**MTF Value**	
	1717TC and 1417TC	**X3C Detector**
1 lp/mm	0.517	0.385
2 lp/mm	0.230	0.134
3 lp/mm	0.123	0.075
3.5 lp/mm	0.063	0.063

Noise Power Spectrum:

A comparison of measured NPS curves show that the 1717TC and 1417TC flat panels have a similar noise performance profile at spatial frequencies as the predicate IDC X3C detector.

Spatial Frequency	NPS Value	
	1717TC and 1417TC	X3C Detector
0 lp/mm	8.01	2.21
1 lp/mm	3.30	0.98
2 lp/mm	1.27	0.82
3 lp/mm	0.64	0.82
3.5 lp/mm	0.58	0.81

B. Environmental, electrical, mechanical safety, and performance testing was completed for the 1717TC and 1417TC, 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 1717TC and 1417TC are substantially equivalent to the IDC X3C 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 1717TC and 1417TC flat panels and compared to images acquired with the IDC X3C 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 proposed 1717TC and 1417TC devices produce images that are diagnostically similar, and slightly superior, to the predicate device. A copy of the images was submitted as part of this special 510(k) submission.

Clinical Test Summary:

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

"Clinical images were provided; these images were not necessary to establish substantial equivalence based on the modifications to the device (note x-ray system that uses previously cleared detectors) but they provide further evidence in addition to bench testing data to show that the complete system works as intended."

8. Conclusion:

The Aquarius 8600 1717TC and Aquarius 8600 1417TC medical devices have identical indications for use, and similar technological characteristics as the IDC X3C predicate device.

The flat panel components for the Aquarius 8600 1717TC and Aquarius 8600 1417TC are identical to the flat panels listed as reference devices (cleared separately in K102123 and K122919), and employs the same software as the IDC X3C predicate device.

The Aquarius 8600 1717TC and Aquarius 8600 1417TC devices are dimensionally smaller and lighter in weight than the predicate IDC X3C detector, which results in a safer medical device.

The proposed Aquarius 8600 1717TC and Aquarius 8600 1417TC 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 1717TC and Aquarius 8600 1417TC are substantially equivalent in comparison with the IDC X3C predicate device as described herein.