Imaging Dynamics Company Ltd.
% Daniel Kamm, P.E.
Principal Engineer
Kamm & Associates
8870 Ravello Ct.
NAPLES FL 34114

November 9, 2017

Re: K173273
Trade/Device Name: Aquarius 8600 1417WCI; Aquarius 8600 1717WCI
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: October 4, 2017
Received: October 12, 2017

Dear Daniel Kamm:

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.

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.

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,

Robert 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)*
K173273

Device Name
Aquarius 8600 1417WCI; Aquarius 8600 1717WCI

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 K173273

1. Submitter: Name –

Imaging Dynamics Company
Suite 130, 3510-29th Street NE
Calgary, Alberta, Canada T1Y 7E5
Tel: 403.251.9939
Fax: 403.251.1771
www.imagingdynamics.com
Contact – Nicole Wherry
Date prepared: September 7, 2017

2. Identification of the Device:
Device: Aquarius 8600 1417WCI; Aquarius 8600 1717WCI
Classification Name: Stationary x-ray system
Product Code: MQB
Common/Usual Name: Stationary x-ray system (digital)
Device Class/Regulation Number: Class II per 21 CFR 892.1680

3. Predicate Device: Manufacturer: Imaging Dynamics Company
Device: Aquarius 8600 1417TC/1717TC
Number: K170202
Classification Name: Stationary x-ray system
Product Code: MQB
Common/Usual Name: Stationary x-ray system (digital)
Device Class/Regulation Number: Class II per 21 CFR 892.1680

4. Reference Device: K160810

Trade name:	ViZion DR + Wireless
Regulation name:	Stationary x-ray system.
Regulation number:	21 CFR 892.1680
Product code:	MQB
Device class:	Class II.

The flat panel detector integrated into the Aquarius 8600 1417WCI is identical to the flat panel detector cleared in K160810

5. A description of the device: This device is a medical x-ray image acquisition device. X-rays generated by X-ray generator/ tube that penetrate patient's body are converted to a digital file by the detector. After that the detector sends this digital file to a pc where the companion software has been installed. This software was cleared in our previous submission, K170202. A monitor displays this image. Images can then be transferred via the DICOM protocol. This device is nearly identical to the predicate but now the digital panels have Wi-Fi in addition to Ethernet interfaces. The Aquarius 8600 will be marketed in two possible configurations:
Aquarius 8600 1717WCI (tethered or wireless), 17 x 17 inch flat panel as a retrofit package with Magellan software).
Aquarius 8600 1417WCI (tethered or wireless), 14 x 17 inch flat panel as a retrofit package with Magellan software).

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.

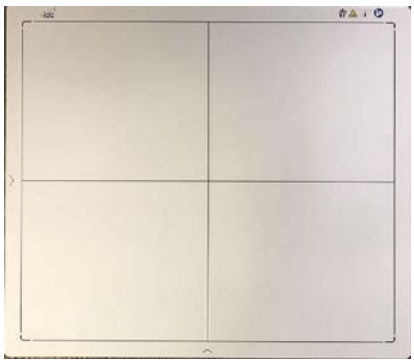
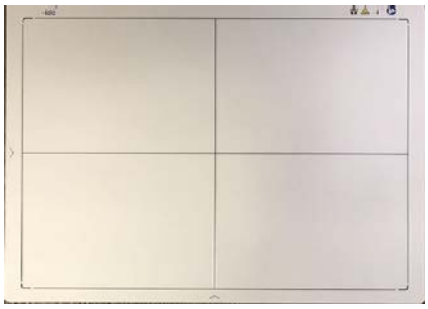
Generator	Property	Power Requirement
40 kW CMP 200 DR X-ray generator	Line Voltage	208 VAC – 5% to 230 VAC + 10%, 1 phase 208 VAC – 5% to 230 VAC + 10%, 3 phase 400 VAC ± 10%, 3 phase 480 VAC ± 10%, 3 phase
	Line Frequency	50/60 Hz
	Momentary Current	275 Amps at 208 VAC (1 phase) 154 Amps/phase at 208 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

6. Indications for Use: 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. (Rx Only)

7. The Magellan 1417WCI/Magellan 1717WCI panels have essentially the same technological characteristics (i.e., design, material, chemical composition, energy source) as the predicate device. See the comparison table below.

Comparison Table

Characteristic	Aquarius 8600 Aquarius 8600 1417TC/1717TC K170202 Imaging Dynamics Company	Aquarius 8600 1417WCI; Aquarius 8600 1717WCI Imaging Dynamics Company
Indications	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. (Rx Only)	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. (Rx Only) (EXACTLY THE SAME)
Panel Communi-cation	Tethered Gigabit Ethernet	Tethered Gigabit Ethernet or Wireless via previously cleared panel (K160810)
Sensor Type	Amorphous Silicon, TFT	Amorphous Silicon, TFT
Scintillator	CsI:Tl	CsI:Tl
Panel Resolution	2816 x 3328 or 3328 x 3328	2304 x 2800 or 3072 x 3072
Panel Size	14x17 inches or 17 X 17 inches	14x17 inches or 17 X 17 inches SAME
Pixel Size	127 µm	150 µm. (14x17) or 139 µm (17x17) NOT A MEANINGFUL DIFFERENCE
Resolution	3.9 lp/mm	3.59 lp/mm or 3.33 lp/mm NOT A MEANINGFUL DIFFERENCE
Image depth	14 bits	14 bits SAME
Preview Image	2 seconds	Less than 3 seconds EQUIVALENT
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
DICOM	Yes	SAME
Safety/EMC	EN/IEC 60601-1, Safety EN/IEC 60601-1-2 EMC	SAME
Operating Environment	Storage and transportation Conditions: Temperature -10 to +50°C Humidity 10 to 80%	SAME
MTF @1 lp/mm	14 x 17: 0.608 17 x 17: 0.517	14 x 17: 0.667 17 x 17: 0.706 The new panels have slightly better MTF
DQE (0)	14 x 17: 0.74 17 x 17: 0.68	14 x 17: 0.40 17 x 17: 0.53 The new panels have slightly lower DQE
Trigger	Auto sense or manual	SAME

Characteristic	Aquarius 8600 Aquarius 8600 1417TC/1717TC K170202 Imaging Dynamics Company	Aquarius 8600 1417WCI; Aquarius 8600 1717WCI Imaging Dynamics Company
Power Source	100 -250V ~ 50/60Hz 250V ~	100 -250V ~ 50/60Hz 250V OR Rechargeable Battery
Photo	 	 

Comparison Conclusion:

The proposed new device has the following similarities to the predicate:

a) Sensor Type
c) Active Area
d) Sensor Pixel
e) Dimensions
f) Performance characteristics.
g) IDENTICAL Indications for Use

The main difference is the new proposed panels may operate wirelessly or tethered, whereas the predicate panels could only work tethered.

8. Description of non-clinical tests. The unit has undergone electrical safety and electromagnetic compatibility testing, as well as integration validation and risk analysis. Bench testing for imaging characteristics such as MTF and DQE was performed in accordance with the FDA Guidance Document on Solid State Imaging Devices: ***"Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices."*** Labeling complies with FDA guidelines.
   Testing was performed in accordance with the following standards:

   a. IEC 60601-1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
   b. IEC 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for safety; Collateral standard: Electromagnetic compatibility; Requirements and tests
   c. NEMA PS 3.1~PS 3.18 Digital Imaging and Communications in Medicine (DICOM)][7/31/2008]
   d. IEC 60601-2-54 Particular requirements for basic safety and essential performance of X-ray equipment for radiography and radioscopy

e. IEC 62133 Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications.
f. Our device software and labeling has addressed cybersecurity via reference to the FDA's cybersecurity guidance: ***"Content of Premarket Submissions for Management of Cybersecurity in Medical Devices."*** It was used in the development of the device and precautions were added to the labeling.

9. Description of clinical tests. 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.

10. Conclusions drawn: The nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device identified in paragraph 3, above.