May 24, 2018

PIXXGEN Corporation
% Mr. Daniel Kamm
Principal Engineer
Kamm & Associates
8870 Ravello Ct
NAPLES FL 34114

Re: K180976
Trade/Device Name: PIXX 1717; PIXX 1417; PIXX 1212; Digital Diagnostic X-Ray Receptor Panels
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: April 25, 2018
Received: April 27, 2018

Dear Mr. 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, 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)*
K180976

Device Name
PIXX 1717; PIXX 1417; PIXX 1212; Digital Diagnostic X-Ray Receptor Panels

Indications for Use *(Describe)*
Indicated for use in general radiographic images of human anatomy. It is intended to replace radiographic film/screen systems in all general-purpose diagnostic procedures, excluding fluoroscopic, angiographic, and mammographic applications

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

510(k) Number K180976

PIXXGEN Corporation
5F, SMART BAY, 123, Beolmal-ro, Dongan-gu,
Anyang-si, Gyeonggi-do, 14056, Korea
Tel +82.70.4846.8888

Date Prepared: May 18, 2018

Contact: Young Kim, President

1. **Identification of the Device:**
   Proprietary-Trade Names: PIXX 1717; PIXX 1417; PIXX 1212; Digital Diagnostic X-Ray Receptor Panels

Device:	**Solid State X-Ray Imager (Flat Panel/Digital Imager)**
Regulation Name:	**Stationary x-ray system.**
Product Code:	**MQB**
Regulation Number:	**892.1680**
Device Class:	**2**

2. **Equivalent legally marketed device**: ATAL 9, K152151, Atlaim Corporation. (Company name changed now to Pixxgen Corporation)

Device:	**Solid State X-Ray Imager (Flat Panel/Digital Imager)**
Regulation Name:	**Stationary x-ray system.**
Product Code:	**MQB**
Regulation Number:	**892.1680**
Device Class:	**2**

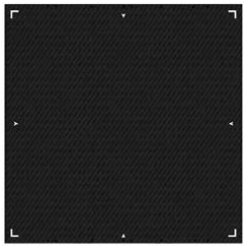
3. **Indications for Use (intended use)** Indicated for use in general radiographic images of human anatomy. It is intended to replace radiographic film/screen systems in all general-purpose diagnostic procedures, excluding fluoroscopic, angiographic, and mammographic applications.

4. **Description of the Device**:
   The PIXX series are digital radiography systems, featuring an integrated flat panel digital detector (FPD). They are designed to perform digital radiographic examinations as a replacement for conventional film. This integrated platform provides the benefits of PACS with the advantages of digital radiography for a filmless environment and improves cost effectiveness. The major functions and principle of operation of the updated panels are the same as our previous panel retaining the Wi-Fi wireless features.

5. **Safety and Effectiveness, comparison to predicate device**. The results of clinical image inspection, bench, and test laboratory results indicates that the new device is as safe and effective as the predicate device. Clinical images collected demonstrate equal or better image quality as compared to our predicate.

6. **Substantial Equivalence Chart**

	ATAL 9, K152151	**PIXX 1717**	**PIXX 1417**	**PIXX 1212**
Intended Use	**Indicated for use in general radiographic images of human anatomy. It is intended to replace radiographic film/screen systems in all general-purpose diagnostic procedures, excluding fluoroscopic, angiographic, and mammographic applications**	UNCHANGED	UNCHANGED	UNCHANGED
Configuration	This submission is for the Digital Panel and Software only, no generator or stand provided.	UNCHANGED	UNCHANGED	UNCHANGED
Pixel Pitch	139um	140um/168um	140 um	140 um
Limiting Resolution	Over 3 lp/mm	SAME	SAME	SAME
DQE(CSI)	At 2 lp/mm 29.5%	At 2 lp/mm 26.5%	At 2 lp/mm 26.5%	At 2 lp/mm 26.5%
MTF(CSI)	At 2 lp/mm 42%	At 2 lp/mm 44%	At 2 lp/mm 44%	At 2 lp/mm 44%
DQE(GOS)	At 2 lp/mm 18	At 2 lp/mm 21	At 2 lp/mm 21	At 2 lp/mm 21
MTF(GOS)	At 2 lp/mm 33%	At 2 lp/mm 35%	At 2 lp/mm 35%	At 2 lp/mm 35%
DQE and MTF Comments	The MTF and DQE measurements are very similar between our predicate and the new PIXX series of digital panels. Some measurements are slightly higher, and some are very slightly lower. The 7% MTF difference for CSI performance is comparable to the possible measurement error.			
A/D Conversion	16 bits	16 bits	16 bits	16 bits
Active Area	17 x 17 inch	17 x 17 inch	14 x 17 inch	12 x 12 inch
Dimensions(mm)/ Weights(Kg)	460(W)x461(L)x15(H)/(2.9Kg w/o Battery)(up to 10 hours of battery life)	460(W)x461(L)x15(H)/ 3.0Kg	385(W) x 460(L) x 15(H)/ 2.8Kg	308.5(W) x 319.5(L) x 15(H)/ 1.9Kg
Pixels	3,072x3,072	3,072 x 3,072	2,560 x 3,072	2,048 x 2,048
Software	Outputs a DICOM image	SAME as K152151 The software is unchanged.	SAME as K152151 The software is unchanged.	SAME as K152151 The software is unchanged.
DICOM	Yes	Yes	Yes	Yes
Scintillator	CsI orGOS	UNCHANGED	UNCHANGED	UNCHANGED
Interface	Wired: Gigabit Ethernet (1000BASE-T) Wireless:IEEE802.11ac, backward compatible	Wired: Gigabit Ethernet (1000BASE-T) Wireless: IEEE802.11ac, backward compatible	Wired: Gigabit Ethernet (1000BASE-T) Wireless: IEEE802.11ac, backward compatible	Wired: Gigabit Ethernet (1000BASE-T) Wireless: IEEE802.11ac, backward compatible
Power source	AC Line and/or Rechargeable Lithium Battery	AC Line	AC Line	AC Line

	ATAL 9, K152151	PIXX 1717	PIXX 1417	PIXX 1212
Standards	Electrical Safety per IEC 60601-1 and EMC per IEC 60601-1-2 as well as IEEE802.11ac. Meets FCC requirements.	Electrical Safety per IEC 60601-1:2012 and EMC per IEC 60601-1-22007+AC:2010 as well as IEEE802.11ac. Meets FCC requirements.	Electrical Safety per IEC 60601-1:2012 and EMC per IEC 60601-1-22007+AC:2010 as well as IEEE802.11ac. Meets FCC requirements.	Electrical Safety per IEC 60601-1:2012 and EMC per IEC 60601-1-22007+AC:2010 as well as IEEE802.11ac. Meets FCC requirements.
Photos				

7. **Summary of Bench Testing Conducted:** IEC Standards were employed for: Electrical Safety, IEC60601-1 and Electromagnetic Compatibility, IEC60601-1-2 as shown in the comparison table above. MTF and DQE measurements, Risk Analysis and Software verification were conducted in accordance with the FDA guidance documents: *Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices Guidance for Industry and Food and Drug Administration Staff and Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.* As expected the DQE and MTF measurements show minimal differences, and the limiting resolution is the same. The software remains the same as in K152151. Wireless communication testing was performed to verify wireless connectivity. The device was also found to comply with FCC requirements for wireless operation. In addition, the following FDA Guidance Documents were consulted during the development of this device: *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, Guidance for Industry and Food and Drug Administration Staff* and *Pediatric Information for X-ray Imaging Device Premarket Notifications.*

8. **Summary of Clinical Testing:** Clinical images were acquired and evaluated by a board certified radiologist who concluded the images from the new panels are as good as or better than the images acquired with the predicate panel, as required by the applicable FDA guidance on solid state imaging devices. The core technology of the panel remains the same.

9. **Conclusion:** After analyzing bench, clinical image, and external laboratory testing to applicable standards, it is the conclusion of Pixxgen that the PIXX 1717; PIXX 1417; PIXX 1212; Digital Diagnostic X-Ray Receptor Panels are as safe and effective as the predicate device, have few technological differences, and has the identical indications for use, thus rendering them substantially equivalent to the predicate device.