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

June 4, 2021

Re: K211108
Trade/Device Name: Prudent 1717, Prudent 1417, Prudent 1212
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MQB
Dated: April 14, 2021
Received: April 15, 2021

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. 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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211108

Device Name
Prudent 1717, Prudent 1417, Prudent 1212

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 K211108

PIXXGEN Corporation
5F, SMART BAY, 123, Beolmal-ro, Dongan-gu,
Anyang-si, Gyeonggi-do, 431804, Korea
Tel +82.70.4846.8888
Date Prepared: April 29, 2021
Contact: Young Kim, President

1. **Identification of the Device:**
   Proprietary-Trade Names: Prudent 1717, Prudent 1417, Prudent 1212
   Classification Name: Solid State X-Ray Imager (Flat Panel/Digital Imager),
   Common/Usual Name: Digital X-Ray Receptor Panel
   Device Class/Regulation Number: Class II per regulation 892.1680
   Product Code: MQB

2. **Equivalent legally marketed device**: **K182533** PIXX 1717; PIXX 1417; PIXX 1212; Digital Diagnostic X-Ray Receptor Panels
   Classification Name: Solid State X-Ray Imager (Flat Panel/Digital Imager) MQB,
   Common/Usual Name: Digital X-Ray Receptor Panel
   Device Class/Regulation Number: Class II per regulation 892.1680
   Product Code: MQB
   Alternate Predicate Device 1: (for MTF/DQE comparison) K202995, CareRay Digital Medical Technology Co., Ltd
   Proprietary-Trade Name: CareView 3600RF, CareRay Digital Medical Technology Co., Ltd.
   Classification Name: Solid State X-Ray Imager (Flat Panel/Digital Imager),
   Common/Usual Name: Digital X-Ray Receptor Panel
   Device Class/Regulation Number: Class II per regulation 892.1680
   Product Code: MQB
   Alternate Predicate Device 2: (for MTF/DQE comparison) K201932, CareRay Digital Medical Technology Co., Ltd
   Proprietary-Trade Name: CareView 1800Cw, CareRay Digital Medical Technology Co., Ltd.
   Classification Name: Solid State X-Ray Imager (Flat Panel/Digital Imager),
   Common/Usual Name: Digital X-Ray Receptor Panel
   Device Class/Regulation Number: Class II per regulation 892.1680
   Product Code: MQB

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 Prudent 1717, Prudent 1417, Prudent 1212 are digital radiography systems, featuring an integrated flat panel digital detector (FPD). It is 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 and rechargeable battery operation. The Prudent 1717 is

available in 3 pixel sizes: 100/140/168 µm whereas the Prudent 1417, Prudent 1212 are available in two pixel sizes: 100/140 µm. The available resolutions vary according to the comparison table below. All of the models are Wi-Fi wireless (or wired) and rechargeable battery (or AC line) operated. The device employs the same software as cleared in the predicate with only minor changes made.

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**

	K182533, PIXX 1717, PIXX 1417, PIXX 1212	**Prudent 1717, Prudent 1417, Prudent 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
Configuration	This submission is for the Digital Panel and Software only, no generator or stand provided.	UNCHANGED
Pixel Pitch	140 µm	Prudent 1717: 100/140/168 µm (3 available pixel sizes) Prudent 1417: 100/140 µm (2 available pixel sizes) Prudent 1212: 100/140 µm (2 available pixel sizes)
Limiting Resolution	3 lp/mm	5.0 lp/mm, 3.6 lp/mm 3.0 lp/mm (Equal or better)
A/D Conversion	16 bits	SAME
Active Area	17 x 17 inch 14 x 17 inch 12 x 12 inch	SAME
Dimensions(mm)/ Weights(Kg)	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	460(W)X460(L)X15(H)/ 3.9Kg 382(W)X460(L)X15(H)/ 3.3Kg 372(W)X315(L)X15(H)/ 2.0Kg Comparable sizes
Pixels	3,072 x 3,072 2,560 x 3,072 2,048 x 2,048	1717: 3072x3072/2560x2560/ 4302x4302 1417: 2500x3052 / 3534x4302 1212: 2048x2048 / 2864x2864 Similar resolutions
Software	Outputs a DICOM image	SAME
DICOM	Yes	Yes
Scintillator	CsI or GOS	SAME

	K182533, PIXX 1717, PIXX 1417, PIXX 1212	Prudent 1717, Prudent 1417, Prudent 1212
Interface	Wired: Gigabit Ethernet (1000BASE-T) Wireless:IEEE802.11ac, backward compatible	SAME
Power source	AC Line and/or Rechargeable Lithium Battery; 5 hours/300 images	AC Line and/or Rechargeable Lithium Battery; 6~8 hours/480~600 images
Standards	Electrical Safety per IEC 60601-1:2012 and EMC per IEC 60601-1-22007+AC:2010 as well as IEEE802.11ac. Meets FCC requirements plus IEC 62133 Battery safety.	SAME

	Alternate predicates	Prudent 1717, Prudent 1417, Prudent 1212
DQE(CSI)	K201932 Alternate predicate At 2 lp/mm 45%	At 2 lp/mm 60 % / 44% / 47% (@100/140/168 µm respectively) Same or better than alternate predicate
MTF(CSI)	K201932 Alternate predicate at 1 lp/mm: 35%	At 1 lp/mm 70%, 53%, 55% (@100/140/168 µm respectively) Better than alternate predicate
DQE(GOS)	K202995 Alternate predicate at 1 lp/mm 20%	At 1 lp/mm 36%, 27%, 30% (@100/140/168 µm respectively) Better than alternate predicate
MTF(GOS)	K202995 Alternate predicate at 1 lp/mm: 50%	At 1 lp/mm 56%, 55%, 54% (@100/140/168 µm respectively) Better than alternate predicate

7. Summary of Bench Testing Conducted: IEC Standards were employed for: Electrical Safety and Electromagnetic Compatibility, and Battery Safety Tests. Standards met:
Electrical safety per: IEC/UL 60601-1, Medical Electrical Equipment – Part 1: General Requirements for Safety. (General)
Electromagnetic Compatibility per IEC 60601-1-2, Collateral Standard: Electromagnetic compatibility Requirements and tests.
IEC 62133 Edition 2.0 2012-12 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

Risk Analysis was conducted in accordance with ISO 14971:2012 and EN 62304. The software remains essentially the same as in K182533 but moved from Revision 4 to Revision 5. A Software Validation Report for Revision 5 was produced.

MTF and DQE measurements were made in accordance with Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices Guidance for Industry and Food and Drug Administration Staff Document issued on: September 1, 2016

Battery life testing was conducted to confirm that the Prudent panels run for 6-8 hours/480-600 images.

The panels were evaluated for Usability according to IEC 62366-1:2015 Medical devices — Part 1: Application of usability engineering to medical devices. The evaluation concluded that the intended user can safely use the device in the intended environment without use error.

Cybersecurity precautionary labeling was added per the FDA guidance: Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, Guidance for Industry and Food and Drug Administration Staff, Document Issued on: October 2, 2014.

8. **Summary of Clinical Testing:** Clinical images obtained in accordance with Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices 1 Guidance for Industry and Food and Drug Administration Staff Document issued on: September 1, 2016. The images were evaluated by a Board Certified Radiologist and found to be of excellent diagnostic quality.

9. **Conclusion:** After analyzing bench, clinical image, and external laboratory testing to applicable standards, it is the conclusion of Pixxgen that the Prudent 1717, Prudent 1417, Prudent 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.