October 4, 2018

Pixxgen Corporation
% Daniel Kamm
Principal Engineer
Kamm & Associates
8870 Ravello Ct
Naples, Florida 34114

Re: K182533
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: Class II
Product Code: MQB
Dated: September 12, 2018
Received: September 14, 2018

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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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 A. 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)*

K182533

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

**510(k) Summary**
**510(k) Number K182533**

**PIXXGEN Corporation**
**5F, SMART BAY, 123, Beolmal-ro, Dongan-gu,**
**Anyang-si, Gyeonggi-do, 14056, Korea**
**Tel +82.70.4846.8888**
**Date Prepared: September 28, 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**: **PIXX 1717; PIXX 1417; PIXX 1212; Digital Diagnostic X-Ray Receptor Panels.**
   **Manufacturer:** **PIXXGEN Corporation**
   **510(k) Number:** **K180976**
   **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. (Rx Only)

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. The modification involves adding battery power capability to the devices in our previous submission K180976.

5. **Safety and Effectiveness, comparison to predicate device**. The results of bench and test laboratory results indicates that the new devices are as safe and effective as the predicate devices.

## 6. **Substantial Equivalence Chart**

| | **K180976, PIXX 1717, PIXX 1417, PIXX 1212** | **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 | 140um | SAME | SAME | SAME |
| Limiting Resolution | Over 3 lp/mm | SAME | SAME | SAME |
| DQE(CSI) | At 2 lp/mm 26.5% | SAME | SAME | SAME |
| MTF(CSI) | At 2 lp/mm 44% | SAME | SAME | SAME |
| DQE(GOS) | At 2 lp/mm 21 | SAME | SAME | SAME |
| MTF(GOS) | At 2 lp/mm 35% | SAME | SAME | SAME |
| DQE and MTF Comments | Adding battery power capability did not change the panel performance. | | | |
| A/D Conversion | 16 bits | SAME | SAME | SAME |
| Active Area | 17 x 17 inch<br>14 x 17 inch<br>12 x 12 inch | 17 x 17 inch | 14 x 17 inch | 12 x 12 inch |
| Dimensions(mm)/ Weights(Kg) | 460(W)x461(L)x15(H)/3.0Kg<br>385(W) x 460(L) x 15(H)/ 2.8Kg<br>308.5(W) x 319.5(L) x 15(H)/ 1.9Kg | SAME | SAME | SAME |
| Pixels | 3,072x3,072<br>2,560 x 3,072<br>2,048 x 2,048 | 3,072 x 3,072 | 2,560 x 3,072 | 2,048 x 2,048 |
| Software | Outputs a DICOM image | SAME | SAME | SAME |
| DICOM | Yes | Yes | Yes | Yes |
| Scintillator | CsI orGOS | UNCHANGED | UNCHANGED | UNCHANGED |
| Interface | Wired: Gigabit Ethernet (1000BASE-T)<br>Wireless:IEEE802.11ac, backward compatible | SAME | SAME | SAME |
| Power source | AC Line only | AC Line and/or Rechargeable Lithium Battery;<br>5 hours/300 images | AC Line and/or Rechargeable Lithium Battery;<br>5 hours/300 images | AC Line and/or Rechargeable Lithium Battery 8 hours/480 images |

| | K180976, PIXX 1717, PIXX 1417, PIXX 1212 | PIXX 1717 | PIXX 1417 | PIXX 1212 |
|---|---|---|---|---|
| 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. | SAME plus IEC 62133 Battery safety | SAME plus IEC 62133 Battery safety | SAME plus IEC 62133 Battery safety |

**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 the same as in K180976. MTF and DQE measurements were not needed because the panel characteristics are identical to our predicate cleared earlier this year.
Battery life testing was conducted to confirm that the PIXX 1212 runs for 8 hours/480 images and for the PIXX 1717/1417 for 5 hours/300 images.
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 were not required because the panel technology did not change from K180976.

**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.