510(k) Summary, 510(k) Number K190691

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1. **Identification of the Device:**
   Proprietary-Trade Names: PIXX2430 Digital Diagnostic X-Ray Receptor Panel
   Regulation Number: 21 CFR 892.1680
   Regulation Name: Stationary x-ray system
   Regulatory Class: Class II
   Product Code: MQB

2. **Equivalent legally marketed device**: **K182533 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

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 PIXX2430 is s digital radiography system, 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 panels (K182533, PIXX 1717, PIXX 1417, PIXX 1212) retaining the Wi-Fi wireless features and rechargeable battery operation. The scintillator is CsI only. The only size available is 12 x 10 inch. It operates either wirelessly or by hard wired Ethernet connection. The power source is rechargeable battery, which lasts for 360 images or 6 hours in standby. It has a finer than usual pixel pitch at 85 µm (finer resolution). Our imaging software is unchanged from our predicate device, K182533. Image storage functionality: PIXX2430 supports the internal storage of raw image data. Wireless Information: This digital panel employs the same wireless functionality as our predicate panels (K182533) using IEEE802.11ac, backward compatible. The operational characteristics can be summarized this way: Transfer power, ~ 100mW; Frequency: 2.4 gHz, or 5 gHz. Security, WPA2; Signal range: Approximately 100 feet. Both medical and non-medical devices can use IEEE802.11ac Wi-Fi, and this technology is designed to handle multiple devices using the same technology simultaneously.

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	**PIXX2430**
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	140um	85 µm (finer resolution)
Limiting Resolution	Over 3 lp/mm	5.8 lp/mm (finer resolution)
DQE(CSI)	At 2 lp/mm 26.5%	At 2 lp/mm 50 % (better)
MTF(CSI)	At 2 lp/mm 44%	At 2 lp/mm 60 % (better)
DQE(GOS)	At 2 lp/mm 21	N/A
MTF(GOS)	At 2 lp/mm 35%	N/A
A/D Conversion	16 bits	SAME
Active Area	17 x 17 inch 14 x 17 inch 12 x 12 inch	12 x 10 inch
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	328(W)X265(L)X15(H) / 1.3Kg
Pixels	3,072 x 3,072 2,560 x 3,072 2,048 x 2,048	2816 X 3584
Software	Outputs a DICOM image	SAME
DICOM	Yes	Yes
Scintillator	CsI or GOS	CsI ONLY
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 hours/360 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

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 K182533. 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 PIXX2430 runs for 6 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 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 PIXX2430 Digital Diagnostic X-Ray Receptor Panel is 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.