November 7, 2024

Aspen Imaging Healthcare Inc
% Dave Kim
Regulatory Affairs Consultant
Mtech Group LLC
7505 Fannin St. Suite 610
HOUSTON, TX 77054

Re: K241346
Trade/Device Name: IODR1717 / IODR1417 / IODR1417-GF (Digital Flat Panel X-ray Detector)
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary X-Ray System
Regulatory Class: Class II
Product Code: MQB
Dated: May 6, 2024
Received: October 8, 2024

Dear Dave Kim:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological Imaging
Devices and Electronic Products
OHT8: Office of 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241346

Device Name
IODR1717 / IODR1417 / IODR1417-GF
(Digital Flat Panel X-ray Detector)

Indications for Use *(Describe)*

The IODR1717 / IODR1417 / IODR1417-GF (Digital Flat Panel X-Ray Detector) is indicated as a digital imaging solution designed for providing the general radiographic diagnosis of human anatomy targeting both adults and children. It is intended to replace film-based radiographic diagnostic systems. Not to be used 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
K241346

1. Date Prepared [21 CFR 807.92(a)(a)]
November 4, 2024

2. Submitter's Information [21 CFR 807.92(a)(1)]

Name of Manufacturer:	Aspen Imaging Healthcare Inc.
Address:	801 Jupiter Rd Suite 200, Plano, TX 75074, USA
Contact Name:	Mr. Casey Lee, Vice President
Telephone No.:	(+1) 214-257-0113
Email Address:	casey.lee@aspenimaging.com

3. Official Correspondent

Name:	Dave Kim, MBA
Address:	Mtech Group LLC
	7505 Fannin St. Suite 610
	Houston, TX 77054
Tel:	1-713-467-2607
Email:	davekim@mtechgroupllc.com

4. Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

Trade/Device/Model Name	IODR1717 / IODR1417 / IODR1417-GF (Digital Flat Panel X-ray Detector)
Common Name	Digital Flat Panel X-ray Detector
Device Classification Name	Stationary X-ray System
Regulation Number	21 CFR 892.1680
Classification Product Code	MQB
Device Class	II
510(k) Review Panel	Radiology

5. Identification of Predicate Device(s) [21 CFR 807.92(a)(3)]

The identified predicate device within this submission is shown as follow;

Predicate Device#1

- 510(k) Number: K223930
- Applicant: H&abyz Co., Ltd.
- Detector Name: A1717MCW/A1417MCW/F1417MCW
- Common Name: Digital Diagnostic X-ray System
- Classification Name: System. X-ray, Stationary
- Regulation Number: 21 CFR 892.1680
- Classification Product Code: MQB
- Device Class: II
- 510(k) Review Panel: Radiology

6. Description of the Device [21 CFR 807.92(a)(4)]

The IODR1717 / IODR1417 / IODR1417-GF detectors are wired or wireless digital flat panel detectors that have been designed for faster, more streamlined approach to digital radiography systems. The IODR1717 / IODR1417 / IODR1417-GF detectors utilize a combination of propriety TFT and scintillator (CsI), and those and electronics are housed in one package. The detectors support an auto-trigger signal sensing technology that allows the detectors to be used without generator integration.

The flat panel sensors of The IODR1717 / IODR1417 / IODR1417-GF are fabricated using thin film technology based on amorphous silicon technology. Electronically, the sensors are much like conventional photodiode arrays. Each pixel in the array consists of a light-sensing photodiode and a switching Thin Film Transistor (TFT) in the same electronic circuit. Amorphous silicon photodiodes are sensitive to visible light, with a response curve roughly comparable to human vision. The sensitivity of amorphous silicon photodiodes peaks in green wavelengths, well matched to scintillators such as CsI. The response has the excellent linearity of a charge-integrating-biased photodiode.

AspenView software includes the basic functionality: generator control, detector control, firmware, image acquisition, image calibration and correction, image storage.

- Detector

Device Model Name	IODR1717	IODR1417	IODR1417-GF
Sensor Type	a-Si TFT		
Scintillator	CsI		
Total Pixel Number	3072 x 3072 pixels	2560 x 3072 pixels	
Total Pixel Area	430 x 430mm	358.5 x 430mm	
Effecgtive Pixel Number	3036 x 3040 pixels	2466 x 3040 pixels	
Effective Pixel Area	425.04 x 425.6mm	345.24 x 425.6mm	
Pixel pitch	140um		

Limiting Resolution	Max 3.57lp/mm
Energy Range	40 ~ 150Kv
A/D Conversion	16 bits
Wi-Fi	IEEE 802.11a/b/g/n/ac, 2.4GHz/5GHz
IP Range	IP54
Communication	1Giga-bit Ethernet
Trigger Mode	Normal Mode AED Mode (Auto Exposure Detection Mode)
Packing	1 BOX

7. Indications for use [21 CFR 807.92(a)(5)]

The IODR1717 / IODR1417 / IODR1417-GF (Digital Flat Panel X-Ray Detector) is indicated as a digital imaging solution designed for providing the general radiographic diagnosis of human anatomy targeting both adults and children. It is intended to replace film-based radiographic diagnostic systems. Not to be used for mammography.

8. Technological Characteristics (Equivalence to Predicate Device) [21 CFR 807.92(a)(6)]

The technological characteristics of the subject devices are identical compared to the predicate devices. Provided below is a table summarizing and comparing the technological characteristics of The IODR1717 / IODR1417 / IODR1417-GF and the predicate device:

[Table 1. Comparison of Proposed Device(IODR1717**) to Predicate Devices]**

	Proposed Device	**Predicate Device#1**	**Note**
K Number	K241346	K223930	-
Manufacturer	Aspen Imaging Healthcare Inc.	H&abyz Co., Ltd.	-
Detector Name	IODR1717	A1717MCW	-
Common Name	Digital Flat Panel X-ray Detector	Digital Flat Panel X-ray Detector	Same
Product Code	MQB	MQB	Same
Regulation Number	21 CFR 892.1680	21 CFR 892.1680	Same
510(k) Review Panel	Radiology	Radiology	Same
Indications for Use	The IODR1717 / IODR1417 / IODR1417-GF (Digital Flat Panel X-Ray Detector) is indicated as a digital imaging solution designed for providing the general radiographic diagnosis of human anatomy targeting both adults and children. It is intended to replace film-based radiographic diagnostic systems. Not to be used for mammography. .	A1717MCW is indicated for digital imaging solution designed for providing general radiographic diagnosis of human anatomy targeting both adult and children. It is intended to replace film based radiographic diagnostic systems. Not to be used for mammography.	Same
Scintillator	CsI	CsI	Same

Effective Pixel Area	425.04 x 425.6 mm	425.04 x 425.6 mm	Same
Total Pixel Number	3,072 x 3,072 pixels	3,072 x 3,072 pixels	Same
Pixel Pitch	140um	140um	Same
High Contrast Limiting Resolution (LP/mm)	Max. 3.57	Max. 3.57	Same
Communication	Wired/Wireless	Wired/Wireless	Same
DQE	69% (0.5lp/mm, min.)	69% (0.5lp/mm, min.)	Same
MTF	97% (0.1lp/mm, min.)	97% (0.1lp/mm, min.)	Same
Anatomical Sites	General	General	Same
Exposure Mode	Normal Mode (Manual), AED Mode (Auto Exposure Detection)	Normal Mode (Manual), AED Mode (Auto Exposure Detection)	Same
Wireless	IEEE 802.11a/b/g/n/ac	IEEE 802.11a/b/g/n/ac	Same

[Table 2. Comparison of Proposed Device(IODR 1417) to Predicate Devices**]**

	Proposed Device	**Predicate Device#1**	**Note**
K Number	K241346	K223930	-
Manufacturer	Aspen Imaging Healthcare Inc.	H&abyz Co., Ltd.	-
Detector Name	IODR1417	A1417MCW	-
Common Name	Digital Flat Panel X-ray Detector	Digital Flat Panel X-ray Detector	Same
Product Code	MQB	MQB	Same
Regulation Number	21 CFR 892.1680	21 CFR 892.1680	Same
510(k) Review Panel	Radiology	Radiology	Same
Indications for Use	The IODR1717 / IODR1417 / IODR1417-GF (Digital Flat Panel X-Ray Detector) is indicated as a digital imaging solution designed for providing the general radiographic diagnosis of human anatomy targeting both adults and children. It is intended to replace film-based radiographic diagnostic systems. Not to be used for mammography.	A1417MCW (Digital Flat Panel X-Ray Detector) is indicated for digital imaging solution designed for providing general radiographic diagnosis of human anatomy targeting both adult and children. It is intended to replace film based radiographic diagnostic systems. Not to be used for mammography.	Same
Scintillator	CsI	CsI	Same
Effective Pixel Area	345.24 x 425.6 mm	345.24 x 425.6 mm	Same
Total Pixel Number	2,560 x 3,072 pixels	2,560 x 3,072 pixels	Same

Pixel Pitch	140um	140um	Same
High Contrast Limiting Resolution (LP/mm)	Max. 3.57	Max. 3.57	Same
Communication	Wired/Wireless	Wired/Wireless	Same
DQE	69% (0.5lp/mm, min.)	69% (0.5lp/mm, min.)	Same
MTF	97% (0.1lp/mm, min.)	97% (0.1lp/mm, min.)	Same
Anatomical Sites	General	General	Same
Exposure Mode	Normal Mode (Manual), AED Mode (Auto Exposure Detection)	Normal Mode (Manual), AED Mode (Auto Exposure Detection)	Same
Wireless	IEEE 802.11a/b/g/n/ac	IEEE 802.11a/b/g/n/ac	Same

[Table 3. Comparison of Proposed Device (IODR 1417-GF**) to Predicate Devices]**

	Proposed Device	**Predicate Device#1**	**Note**
K Number	K241346	K223930	-
Manufacturer	Aspen Imaging Healthcare Inc.	H&abyz Co., Ltd.	-
Detector Name	IODR1417-GF	F1417MCW	-
Common Name	Digital Flat Panel X-ray Detector	Digital Flat Panel X-ray Detector	Same
Product Code	MQB	MQB	Same
Regulation Number	21 CFR 892.1680	21 CFR 892.1680	Same
510(k) Review Panel	Radiology	Radiology	Same
Indications for Use	The IODR1717 / IODR1417 / IODR1417-GF (Digital Flat Panel X-Ray Detector) is indicated as a digital imaging solution designed for providing the general radiographic diagnosis of human anatomy targeting both adults and children. It is intended to replace film-based radiographic diagnostic systems. Not to be used for mammography.	F1417MCW (Digital Flat Panel X-Ray Detector) is indicated for digital imaging solution designed for providing general radiographic diagnosis of human anatomy targeting both adult and children. It is intended to replace film based radiographic diagnostic systems. Not to be used for mammography.	Same
Scintillator	CsI	CsI	Same
Effective Pixel Area	345.24 x 425.6 mm	345.24 x 425.6 mm	Same
Total Pixel Number	2,560 x 3,072 pixels	2,560 x 3,072 pixels	Same
Pixel Pitch	140um	140um	Same
High Contrast Limiting Resolution (LP/mm)	Max. 3.57	Max. 3.57	Same

Communication	Wired/Wireless	Wired/Wireless	Same
DQE	71% (0.5lp/mm, min.)	71% (0.5lp/mm, min.)	Same
MTF	98% (0.1lp/mm, min.)	98% (0.1lp/mm, min.)	Same
Anatomical Sites	General	General	Same
Exposure Mode	Normal Mode (Manual), AED Mode (Auto Exposure Detection)	Normal Mode (Manual), AED Mode (Auto Exposure Detection)	Same
Wireless	IEEE 802.11a/b/g/n/ac	IEEE 802.11a/b/g/n/ac	Same

9. Non-Clinical Test summary

The IODR1717 / IODR1417 / IODR1417-GF comply with voluntary standards for electrical safety, electromagnetic compatibility. The following data were provided in support of the substantial equivalence determination:

1) Electrical Safety, Electromagnetic Compatibility and Performance:

The IODR1717 / IODR1417 / IODR1417-GF detectors comply with the electrical safety and electromagnetic compatibility requirements established by the standards.

Standards No.	Standard Title	Version	Publication Year
IEC 60601-1	Medical Electrical Equipment Part 1: General requirements for basic safety and essential performance	2005/AMD2: 2020	2020
IEC 60601-1-2	Medical Electrical Equipment - Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility - Requirements and Tests	60601-1-2 Edition 4.1 2014-02	2020
IEC 62220-1-1	Medical electrical equipment-Characteristics of digital X-ray imaging devices Part 1-1: Determination of the detective quantum efficiency Detectors used in radiographic imaging	62220-1-1 Edition 1.0 2015-03	2015

2) Software Validation

The IODR1717 / IODR1417 / IODR1417-GF contain MODERATE level of concern software. The software was designed and developed according to a software development process and was verified and validated. Software information is provided in accordance with FDA guidance:

- The content of premarket submissions for software contained in medical devices.

4) Performance Test

Imaging performance test has been conducted according to:

- IEC 62220-1, Medical Electrical Equipment – Characteristics of Digital X-ray Imaging Devices – Part 1-1: Determination of the Detective Quantum Efficiency – Detectors Used in Radiographic Imaging.

We select the predicate device #1 in order to demonstrate adequate DQE performance of The IODR1717 / IODR1417 / IODR1417-GF detector. According to the above comparison table, subject device shows the same DQE as the predicate device.

5) Cybersecurity

- Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions

6) Label

- 21 CFR 1020.30, 1020.31
- Pediatric Information for X-ray Imaging Device Premarket Notifications

10. Clinical Test Summary

Clinical data is no provided for this submission.

11. Substantial Equivalence [21 CFR 807.92(b)(1) and 807.92]

The IODR1717 / IODR1417 / IODR1417-GF are identical to the predicate device, K223930 and there is no change that would adversely affect the use of the product. It is substantially equivalent to these devices in indications for use and technology characteristics.

12. Conclusion [21 CFR 807.92(b)(3)]

In according with the Federal Food & Drug and cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification, concludes that The IODR1717 / IODR1417 / IODR1417-GF detectors are substantially equivalent in safety and effectiveness to the predicate device, K223930.