March 20, 2025

DRTECH Corporation
% Yeongsuk An
Assistant Manager
Suite No. 1, 2 Floor/Suite No. 2, 3 Floor
29, Dunchon-daero 541beon-gil
Jungwon-gu, Seongnam-si, Gyeonggi-do, 13216
SOUTH KOREA

Re: K242770
Trade/Device Name: EXPD 114; EXPD 114G; EXPD 114P; EXPD 114PG
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary X-Ray System
Regulatory Class: Class II
Product Code: MQB
Dated: September 13, 2024
Received: February 18, 2025

Dear Yeongsuk An:

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.

Submission Number *(if known)*

K242770

Device Name

EXPD 114;
EXPD 114G;
EXPD 114P;
EXPD 114PG

Indications for Use *(Describe)*

EXPD 114, EXPD 114P, EXPD 114G, EXPD 114PG Digital X-ray detector is indicated for digital imaging solution designed for providing general radiographic diagnosis of human anatomy. This device is intended to replace film or screen based radiographic systems in all general purpose diagnostic procedures. This device is not intended for mammography applications. It is intended for both adult and pediatric populations.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

DRTECH Corporation
Suite No.1, 2 Floor / Suite No. 2, 3 Floor, 29,
Dunchon-Daero 541beon-gil, Jungwon-gu, Seongnam-si,
Gyeonggi-do, South Korea

K242770

510(k) Summary

[As required by 21 CFR 807.92]

This 510(k) summary of safety and effectiveness information is prepared in accordance with 21 CFR 807.92

1. Date Prepared [21 CFR 807.92(a) (1)]

February/18/2025

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

- Name of Sponsor: DRTECH Corporation
- Address: Suite No.1, 2 Floor / Suite No. 2, 3 Floor, 29, Dunchon-daero541 beon-gil, Jungwon-gu, Seongnam-si, Gyeonggi-do, 13216, Republic of Korea
- Contact Name: Yeongsuk, An
- Telephone No.: + 82-31-779-7787
- Fax No.: + 82-31-779-7790
- Email Address : drtechra@drtech.com
- Registration Number: 3005172103
- Name of Manufacturer: Same as Sponsor

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

- Trade Name: EXPD 114; EXPD 114G; EXPD 114P; EXPD 114PG
- Common Name: Digital Flat Panel X-ray Detector
- Classification Name: Stationary X-ray System
- Classification Panel: Radiology
- Classification Regulation: 21 CFR 892.1680
- Product Code: MQB
- Device Class: II

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

- 510(k) Number: K223124
- Applicant: DRTECH Corporation
- Trade Name: EXPD 86P, EXPD 86PG, EXPD 129P, EXPD 129PG
- Classification Name: Radiology
- Classification Panel: Stationary X-ray System
- Classification Regulation: 21 CFR 892.1680
- Product Code: MQB
- Device Class: II

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

<Modification>
Addition of EXPD 114, EXPD 114G, EXPD 114P, EXPD 114PG : The differences between the subject devices and the predicate devices are Dimension , TFT panel material, and Components(optional). The Dimension of Subject devices is shorter than predicate devices.

6. Indication for Use [21 CFR 807.92(a)(5)]

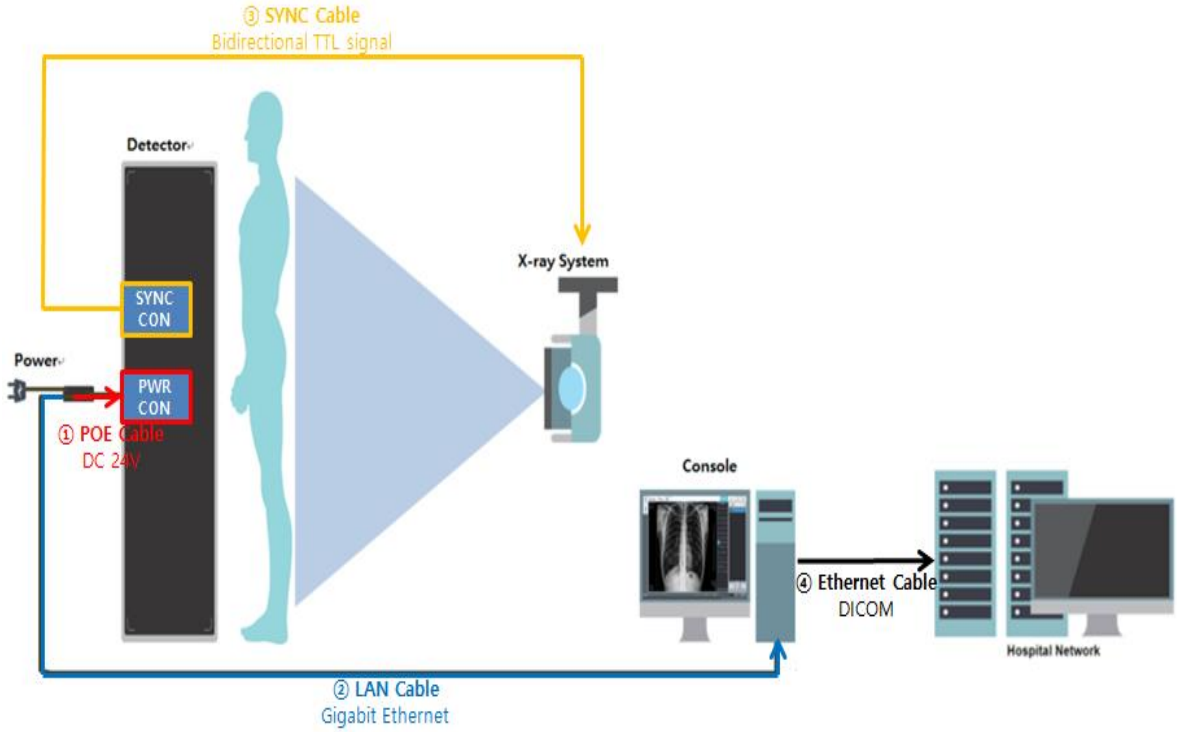
EXPD 114, EXPD 114P, EXPD 114G, EXPD 114PG is indicated for digital imaging solution designed for providing general radiographic diagnosis of human anatomy. This device is intended to replace film or screen based radiographic systems in all general purpose diagnostic procedures. This device is not intended for mammography applications. It is intended for both adult and pediatric populations.

7. Technological Characteristics [21 CFR 807.92(a)(6)]

EXPD 114, EXPD 114G, EXPD 114P, EXPD 114PG are flat-panel type digital X-ray detector that captures projection radiographic images in digital format within seconds, eliminating the need for an entire x-ray film or an image plate as an image capture medium. EXPD 114, EXPD 114G, EXPD 114P, EXPD 114PG differs from traditional X-ray systems in that, instead of exposing a film and chemically processing it to create a hard copy image, a device called a Detector is used to capture the image in electronic form.
EXPD 114, EXPD 114G, EXPD 114P, EXPD 114PG are indirect conversion devices in the form of a square plate in which converts the incoming X-rays into visible light. This visible light is then collected by an optical sensor, which generates an electric charges representation of the spatial distribution of the incoming X-ray quanta.
The charges are converted to a modulated electrical signal through thin film transistors. The amplified signal is converted to a voltage signal and is then converted from an analog to digital signal which can be transmitted to a viewed image print out, transmitted to remote viewing or stored as an electronic data file for later viewing.

8. Integrated Configuration for X-Ray system

EXPD 114, EXPD 114G, EXPD 114P, EXPD 114PG are connected with General diagnostic X-ray system.



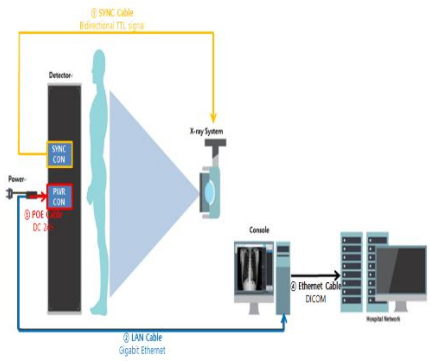
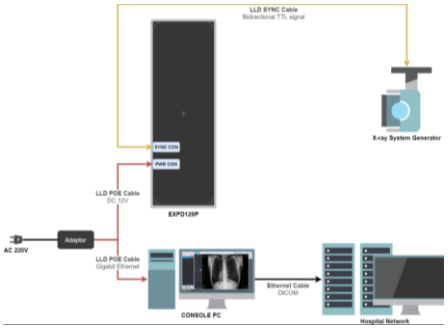
No.	Component	Description
①	POE Cable	1) DC 24V voltage 2) It is supplied from Adaptor to Detector.
②	LAN Cable	1) Gigabit Ethernet Communications 2) It is transmitted from the detector to the CONSOLE PC.
③	SYNC Cable	1) two-way TTL communication 2) It is communicated between the detector and the X-ray System Generator.
④	Ethernet Cable	1) DICOM communication 2) It is transmitted from the CONSOLE PC to the hospital network.

For successful integration of detector with X-ray system, we designed the hardware of EXPD 114, EXPD 114G, EXPD 114P, EXPD 114PG as below function. The Energy of generator is controlled by Radiography imaging software(Econsole2, K240343), not firmware of Detector.

Mode	Description
AED/AWC Mode	The detector detects actual amount of X-rays without any connection to the X-ray generator. No signal used (No need of connector interface cable)
Sync. Trigger Mode	The detector receives EXP_REQ signal that X-ray generator is prepared to generate X-rays. The detector prepares image acquiring and then responds EXP_OK signal to the X-ray generator. The X-ray generator confirms EXP_OK signal and generates X-ray, then the detector performs image acquiring, according to image acquisition time and transmits the image data. EXP_REQ (Generator→ Detector), EXP_OK (Detector →Generator)

9. Substantial Equivalence [21 CFR 807.92(b)]

Parameter		Subject Device	Predicate Device
510(K) Number		Unknown	K223124
Manufacturer		DRTECH Corporation	DRTECH Corporation
Model Name		EXPD 114, EXPD 114G, EXPD 114P, EXPD 114PG	EXPD 86P, EXPD 86PG, EXPD 129P, EXPD 129PG
Classification Name		Stationary X-ray System	Stationary X-ray System
Classification Panel		Radiology	Radiology
Classification Regulation		21 CFR 892.1680	21 CFR 892.1680
Product Code		MQB	MQB
Device Class		Class II	Class II
Intended Use		EXPD 114, EXPD 114P, EXPD 114G, EXPD 114PG is indicated for digital imaging solution designed for providing general radiographic diagnosis of human anatomy. This device is intended to replace film or screen based radiographic systems in all general purpose diagnostic procedures. This device is not intended for mammography applications.	The EXPD 86P/ EXPD 86PG/ EXPD 129P/ EXPD 129PG Digital X-ray detector is indicated for digital imaging solution designed for providing general radiographic diagnosis of human anatomy. This device is intended to replace film or screen based radiographic systems in all general purpose diagnostic procedures. This device is not intended for mammography applications.
Design	Panel Shape	Rectangular Panel	EXPD 129P, EXPD 129PG, EXPD 86P, EXPD 86PG : Rectangular Panel
	Detector Size	17” × 46”	EXPD 129P, EXPD 129PG : 17” × 51”
			EXPD 86P, EXPD 86PG : 17” × 34”
	Dimensions	460mm (W) × 1,178mm (L) × 20mm (H) [±0.5mm]	EXPD 129P, EXPD 129PG : 460mm (W) × 1324mm (L) × 20mm (H) [±0.5mm] EXPD 86P, EXPD 86PG : 460mm (W) × 894.14mm (L) × 15.5mm (H) [±0.5mm]
	Pixel Pitch	140µm	140µm
	Image Size	3,072 × 8,192	EXPD 129P, EXPD 129PG : 3,072 × 9,216 EXPD 86P, EXPD 86PG : 3,072 × 6,144

Parameter		Subject Device	Predicate Device
Panel & Scintillator Materials		Panel Material - EXPD 114, EXPD 114G: TFT – amorphous Silicon - EXPD 114P, EXPD 114PG : TFT – IGZO	TFT – amorphous Silicon
		Scintillator Material EXPD 114, EXPD 114P: CsI EXPD 114G, EXPD 114PG: Gadox,	Scintillator Material - EXPD 129P, EXPD 86P: CsI - EXPD 129PG, EXPD 86PG: Gadox
Perfor-mance	DQE	EXPD 114 : 45% @0.5lp/mm EXPD 114G : 25% @0.5lp/mm EXPD 114P : 45% @0.5lp/mm EXPD 114PG : 25% @0.5lp/mm	EXPD 129P, EXPD 86P : 50.0 % at 0.5 lp/mm EXPD 129PG, EXPD 86PG : 25.0 % at 0.5 lp/mm
	MTF	EXPD 114 : 40% @2.0lp/mm EXPD 114G : 40% @2.0lp/mm EXPD 114P : 40% @2.0lp/mm EXPD 114PG : 40% @2.0lp/mm	EXPD 129P, EXPD 86P : 45.0 % at 2.0 lp/mm EXPD 129PG, EXPD 86PG : 45.0 % at 2.0 lp/mm
	Resolution	3.5 lp/mm	3.5 lp/mm
Anatomical Sites		General Radiography	General Radiography
Power Supply		100-240V~, 50-60 Hz	100~240V~, 50/60 Hz
Components		Adaptor & AC Power Cord POE Cable SYNC Cable LAN Cable	Adaptor & AC Power Cord LLD POE Cable LLD Sync Cable
Communication Interface		Wired: Ethernet	Wired: Ethernet
Diagram			

When compared to the predicate devices (K223124), the EXPD 114, EXPD 114G, EXPD 114P, EXPD 114PG presented in this submission have similar:

- Intended Use
- Technological characteristics
- Operating principle
- Performance (Resolution)
- Communication Method

A few differences are as follows

- Image Size
- Active area
- TFT panel
- MTF and DQE
- Components (optional)

10. Summary of Non-Clinical Data [21 CFR 807.92(b)(1)]

For Performance

The non-clinical performance testing(Bench Test) and Concurrence Study constrains the main physical values for comparison of X-ray devices like DQE and MTF are basically equal or worth the predicate device as the following table:

Parameter	Subject Device	Predicate Device
DQE	EXPD 114 : 45% @0.5lp/mm EXPD 114G : 25% @0.5lp/mm EXPD 114P : 45% @0.5lp/mm EXPD 114PG : 25% @0.5lp/mm	EXPD 129P, EXPD 86P : 50.0 % at 0.5 lp/mm EXPD 129PG, EXPD 86PG : 25.0 % at 0.5 lp/mm
MTF	EXPD 114 : 40% @2.0lp/mm EXPD 114G : 40% @2.0lp/mm EXPD 114P : 40% @2.0lp/mm EXPD 114PG : 40% @2.0lp/mm	EXPD 129P, EXPD 86P : 45.0 % at 2.0 lp/mm EXPD 129PG, EXPD 86PG : 45.0 % at 2.0 lp/mm

For Firmware

Firmware Validation and Verification has been conducted according to the FDA guidance document "Content of Premarket Submissions for Device Software Functions".

For Cybersecurity

Cybersecurity Testing was performed in accordance with the guidance of "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions ".

And The EXPD 114, EXPD 114G, EXPD 114P, EXPD 114PG comply with the following international and FDA-recognized consensus standards:

Recognition No.	Standard No.	Title of Standard	Date of Recognition	Remark
5-125	ISO 14971 Third Edition 2019-12	Medical devices - Application of risk management to medical devices	12/23/2019	
19-46	ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) [Including Amendment 2 (2021)]	05/30/2022	

Recognition No.	Standard No.	Title of Standard	Date of Recognition	Remark
19-36	IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	12/21/2020	
5-132	IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	12/21/2020	
5-129	IEC 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION	Medical devices - Part 1: Application of usability engineering to medical devices	07/06/2020	
13-79	IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION	Medical device software - Software life cycle processes	01/14/2019	
12-349	NEMA PS 3.1 - 3.20 2022d	Digital Imaging and Communications in Medicine (DICOM) Set	12/19/2022	
12-289	IEC 62220-1-1 Edition 1.0 2015-03	Medical electrical equipment- Characteristics of digital X-ray imaging devices Part 1-1: Determination of the detective quantum efficiency Detectors used in radiographic imaging	08/14/2015	

11. Summary of Clinical Data[21 CFR 807.92(b)(2)]

Our Concurrence Study for Image Quality was based on body parts (Chest, C-spine AP, L-spine AP, Shoulder AP, Pelvis AP, Extremity) to compare subject device and predicate device(K223124). In this Concurrence Study, a qualified clinical expert confirmed that the image quality of the subject device is equivalent to that of the predicate device, demonstrating that the subject device meets the diagnostic quality of the predicate device.

12. Related FDA Guidance documents

We reviewed the below FDA guidance documents and it was reflected in the development of the modified EXPD 114, EXPD 114G, EXPD 114P, EXPD 114PG.

Title of Guidance	Remark
Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices	
Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions	
Content of Premarket Submissions for Device Software Functions	
Pediatric Information for X-ray Imaging Device Premarket Notifications	

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

The modified EXPD 114, EXPD 114G, EXPD 114P, EXPD 114PG are substantially equivalent to the currently marketed and predicate device (K223124) in terms of fundamental scientific technology, indications for use, and safety and effectiveness.
Additionally, Substantial equivalence was demonstrated through the non-clinical performance such as Bench Test, Software Validation and Verification, Cybersecurity Testing, which complied with the requirements specified in the international and FDA-recognized consensus standards, ANSI AAMI ES60601-1:2005/AMD2:2021, IEC 60601-1-2:2020, IEC 60601-1-6 Edition 3.2, IEC 62304:2015, IEC 62220-1-1, IEC 81001-5-1 and ANSI UL 2900-1. which complied with the requirements specified in the CDRH's Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices.
Plus, A Concurrence Study was conducted to confirm the clinical equivalence of the subject device with the predicate device. Through the clinical study, it was confirmed that the image quality of the subject device is equivalent to that of the predicate device.

The results of these data demonstrate that EXPD 114, EXPD 114G, EXPD 114P, EXPD 114PG meet the acceptance criteria and are adequate for this intended use. The comparison of technological characteristics, non-clinical performance data, and safety testing demonstrates that the device is as safe, as effective, and performs as well or better than the predicate devices.