August 1, 2023

DRTECH Corporation
℅ Lee Youna
Assistant Manager
Suite No.1, 2 Floor/Suite No. 2, 3 Floor, 29, Dunchon-Daero
541 Beon-Gil, Jungwon-Gu
Seongnam-si, Gyeonggi-do 13216
SOUTH KOREA

Re: K231959
Trade/Device Name: EXPD 4357, EXPD 4357P
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary X-Ray System
Regulatory Class: Class II
Product Code: MQB
Dated: June 30, 2023
Received: July 3, 2023

Dear Lee Youna:

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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231959

Device Name
EXPD 4357, EXPD 4357P

Indications for Use *(Describe)*
The EXPD 4357, EXPD 4357P 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.

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

[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)]

06/30/2023

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: Minjeong Kim
- Telephone No.: + 82-31-779-7710
- 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 4357, EXPD 4357P
- 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: Stationary X-ray System
- Classification Panel: Radiology
- 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 4357, EXPD 4357P : 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)]

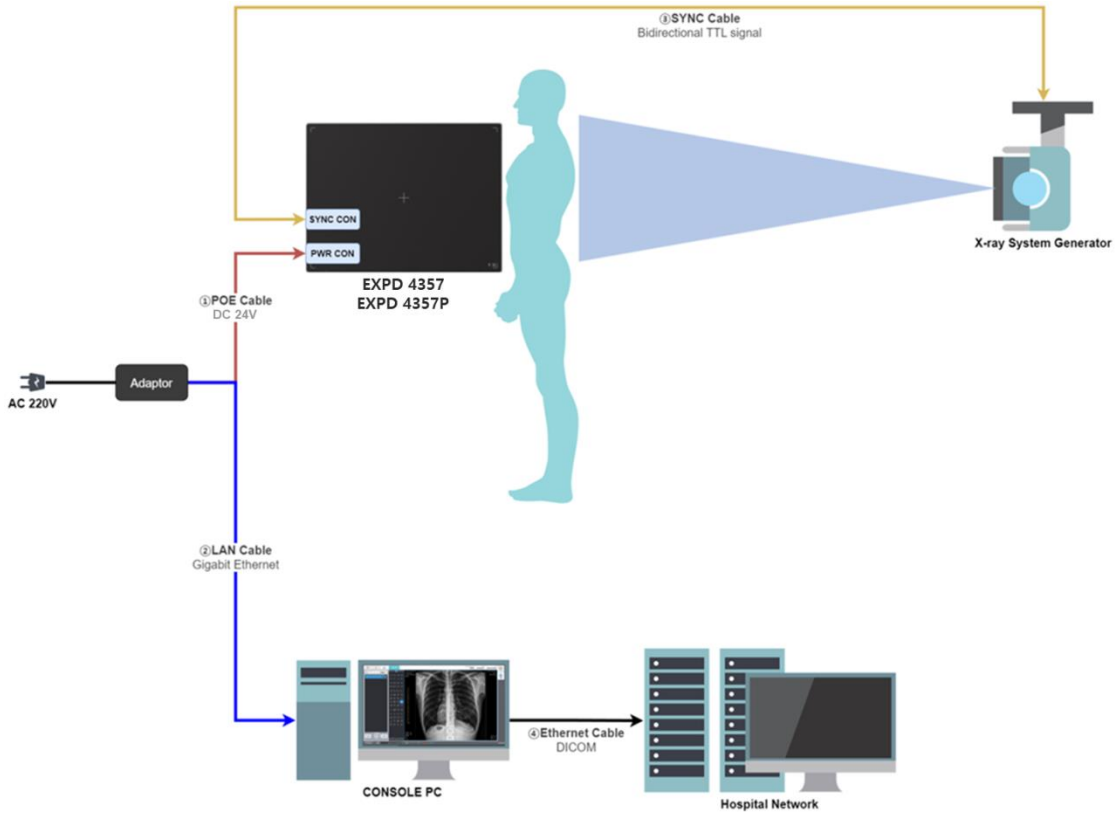
The EXPD 4357, EXPD 4357P Digital X-ray detector is indicated for digital imaging solution designed for providing general radiographic diagnosis of human anatomy. This device is intended to replace film or screen based radiographic systems in all general purpose diagnostic procedures. This device is not intended for mammography applications.

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

The EXPD 4357, EXPD 4357P 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 4357, EXPD 4357P 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.
The EXPD 4357, EXPD 4357P Detector 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

The EXPD 4357, EXPD 4357P 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 4357, EXPD 4357P as below function. The Energy of generator is controlled by Radiography imaging software(Econsole1, K152172), 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 4357, EXPD 4357P	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	The EXPD 4357, EXPD 4357P 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.	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

Parameter		Subject Device	Predicate Device
			mammography applications
Design	Panel Shape	Rectangular Panel	EXPD 129P, EXPD 129PG, EXPD 86P, EXPD 86PG : Rectangular Panel
	Detector Size	17” × 22”	EXPD 129P, EXPD 129PG : 17” × 51”
			EXPD 86P, EXPD 86PG : 17” × 34”
	Dimensions	604mm (W) × 460mm (L) × 15.5mm (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	140㎛	140㎛
	Image Size	3,072 × 7,096	EXPD 129P, EXPD 129PG : 3,072 × 9,216 EXPD 86P, EXPD 86PG : 3,072 × 6,144
Panel & Scintillator Materials		Panel Material - EXPD 4357 : TFT – amorphous Silicon - EXPD 4357P : TFT – IGZO	TFT – amorphous Silicon
		Scintillator Material : CsI	Scintillator Material - EXPD 129P, EXPD 86P: CsI - EXPD 129PG, EXPD 86PG: Gadox
Perfor-mance	DQE	Typ. 55.0 % at 0.5 lp/mm	EXPD 129P, EXPD 86P : 50.0 % at 0.5 lp/mm EXPD 129PG, EXPD 86PG : 25.0 % at 0.5 lp/mm
	MTF	Typ. 45.0 % at 2.0 lp/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

Parameter	Subject Device	Predicate Device
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

When compared to the predicate devices (K223124), the EXPD 4357, EXPD 4357P presented in this submission have similar:

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

A few differences are as follows

- Size
- Performance (DQE and MTF)
- Panel Material
- Components

There are no significant differences between the EXPD 4357, EXPD 4357P and the predicate device(s) that would adversely affect the use of the product. It is substantially equivalent to these devices in design, function, materials, operational principles and intended use.
According to bench test report, it is proved that the DQE and MTF of predicated device and subject device are basically equal or worth than the predicate device. As a result, subject devices performance is equal or worth than the predicate device..

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

The non-clinical performance testing 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	Typ. 55.0 % at 0.5 lp/mm	EXPD 129P, EXPD 86P : 50.0 % at 0.5 lp/mm EXPD 129PG, EXPD 86PG : 25.0 % at 0.5 lp/mm
MTF	Typ. 45.0 % at 2.0 lp/mm	EXPD 129P, EXPD 86P : 45.0 % at 2.0 lp/mm EXPD 129PG, EXPD 86PG : 45.0 % at 2.0 lp/mm

The EXPD 4357, EXPD 4357P detector 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	
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	

Recognition No.	Standard No.	Title of Standard	Date of Recognition	Remark
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. Related FDA Guidance documents

We reviewed the below FDA guidance documents and it was reflected in the development of the modified EXPD 4357, EXPD 4357P detector.

Title of Guidance	Remark
Content of Premarket Submissions for Management of Cybersecurity in Medical Devices	
Pediatric Information for X-ray Imaging Device Premarket Notifications	
Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices	

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

The modified EXPD 4357 and EXPD 4357P detectors 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, 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 and IEC 62220-1-1 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.
The results of these tests demonstrate that The EXPD 4357 and EXPD 4357P 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.