November 16, 2023

DRTECH Corporation
% Kim Minjeong
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: K232753
Trade/Device Name: EXPD 4343D, EXPD 3643D
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MQB
Dated: September 8, 2023
Received: October 23, 2023

Dear Kim Minjeong:

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.

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 Radiologic 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)*
K232753

Device Name
EXPD 4343D, EXPD 3643D

Indications for Use *(Describe)*

The EXPD 4343D and EXPD 3643D Digital X-ray detector are indicated for digital imaging solution designed for providing general radiographic diagnosis of human anatomy. This devices are intended to replace film or screen based radiographic systems in all general purpose diagnostic procedures. This devices are 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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DRTECH Corporation
Suite No.1, 2 Floor / Suite No. 2, 3 Floor, 29,
Dunchon-Daero 541beon-gil, Jungwon-gu, Seongnam-si,
Gyeonggi-do, 13216, Republic of Korea

510(k) Summary - K232753

[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)]

09/08/2023

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.: + 82-31-779-7783
- 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 4343D, EXPD 3643D
- 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: K192400
- Applicant: DRTECH Corporation
- Trade Name: EVS 4343A, EVS 3643A
- 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 4343D, EXPD 3643D : The differences between the subject devices and the predicate devices are TFT Panel and performance (MTF & DQE). Predicate devices used Amorphous silicon TFT, however, subject devices use IGZO TFT.

		Subject Device	Predicate Device
Model Name		EXPD 4343D, EXPD 3643D	EVS 4343A, EVS 3643A
TFT panel		IGZO	Amorphous Silicon
Performance	**DQE**	Typ. 55.0 % at 1.0 lp/mm	EVS 4343A: 52.9% at 1.0 lp/mm
			EVS 3643A: 50.5 % at 1.0 lp/mm
	MTF	Typ. 40.0 % at 2.0 lp/mm	EVS 4343A: 44.1% at 2.0 lp/mm
			EVS 3643A: 44.5 % at 2.0 lp/mm

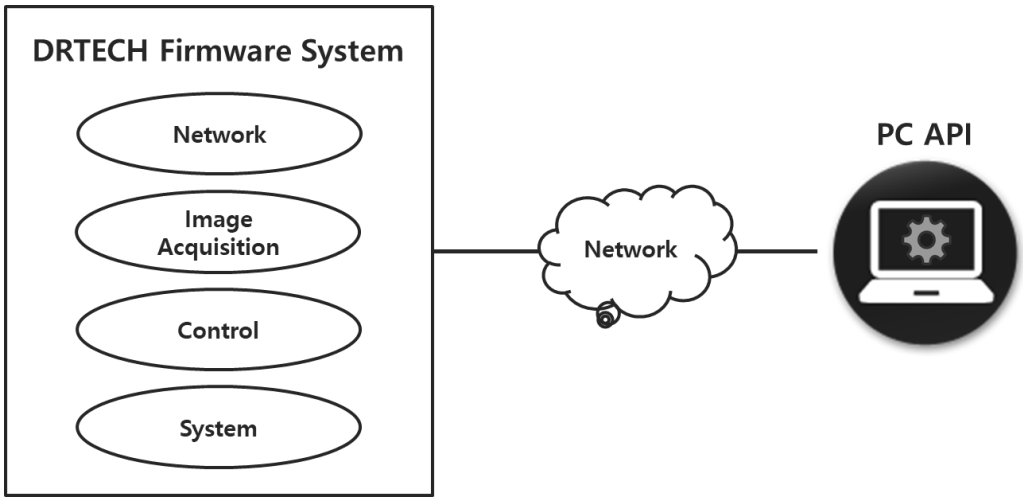
6. Indication for Use [21 CFR 807.92(a)(5)]

The EXPD 4343D and EXPD 3643D Digital X-ray detector are indicated for digital imaging solution designed for providing general radiographic diagnosis of human anatomy. This devices are intended to replace film or screen based radiographic systems in all general purpose diagnostic procedures. This devices are not intended for mammography applications.

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

The EXPD 4343D, EXPD 3643D 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 4343D, EXPD 3643D 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 4343D, EXPD 3643D 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.

1) Firmware
- Level of Concern : Moderate
: DRTECH Firmware includes System Module, Control Module, Image Acquisition Module, Network Module. System Module performs various tasks and initialization for stable system operation and manages the overall system. The control module controls electronic equipment necessary for the detector system drive to S / W and operates according to the purpose. The Image Acquisition Module obtains the image according to the scenario required from PC. The obtained image is assigned to the memory. The network module transmits and receive the information which is necessary for the system drive and image acquisition to the TCP / IP Socket communication.



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

Parameter		Subject Device	Predicate Device
510(K) Number		Unknown	K192400
Manufacturer		DRTECH Corporation	DRTECH Corporation
Model Name		EXPD 4343D, EXPD 3643D	EVS 4343A, EVS 3643A
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 4343D, EXPD 3643D Digital X-ray detector are indicated for digital imaging solution designed for providing general radiographic diagnosis of human anatomy. This devices are intended to replace film or screen based radiographic systems in all general purpose diagnostic procedures. This devices are not intended for mammography applications.	The EVS 4343A / EVS 3643A 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	EXPD 4343D : Square Panel	EVS 4343A: Square Panel
		EXPD 3643D : Rectangular Panel	EVS 3643A: Rectangular Panel
	Detector Size	EXPD 4343D : 17” x 17”	EVS 4343A: 17” x 17”
		EXPD 3643D : 13” x 17”	EVS 3643A: 13” x 17”
	Dimensions	EXPD 4343D : 460(W) x 483(L) x 15.5(H)	EVS 4343A : 460(W) x 483(L) x 15.5(H)
		EXPD 3643D : 460(W) × 409 (L) × 15.5 (H)	EVS 3643A : 460(W) × 409(L) × 15.5(H)
	Pixel Pitch	140μm	140μm
	Image Size	EXPD 4343D: 3,072 x 3,072	EVS 4343A: 3,072 x 3,072
		EXPD 3643D: 2,560 x 3,072	EVS 3643A: 2,560 x 3,072
Panel & Scintillator Materials		Panel Material : TFT – IGZO	Panel Material : TFT – amorphous Silicon
		Scintillator Material : CsI	Scintillator Material : CsI

Parameter		Subject Device	Predicate Device
Perfor-mance	DQE	Typ. 55.0 % at 1.0 lp/mm	EVS 4343A: 52.9% at 1.0 lp/mm
			EVS 3643A: 50.5 % at 1.0 lp/mm
	MTF	Typ. 40.0 % at 2.0 lp/mm	EVS 4343A: 44.1% at 2.0 lp/mm
			EVS 3643A: 44.5 % 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		POE Adaptor & AC Power Cord LAN Cable A LAN Cable B SYNC Cable	PoE Adaptor Lan cables(2 ea) AC Power Cable Ethernet Connector Bracket
Communication Interface		Wired: Ethernet	Wired: Ethernet
Software (Image Processing Program)		EConsole1(K152172)	EConsole1(K152172)

When compared to the predicate devices (K192400), the EXPD 4343D, EXPD 3643D presented in this submission have similar:

- Intended Use
- Technological characteristics
- Operating principle
- Performance (Resolution)
- Communication Method
- Components
- Size Intended Use
- Software (Image Processing Program)

A few differences are as follows

- Panel Material
- Performance (DQE and MTF)

There are no significant differences between the EXPD 4343D, EXPD 3643D 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 1.0 lp/mm	EVS 4343A: 52.9% at 1.0 lp/mm
		EVS 3643A: 50.5 % at 1.0 lp/mm
MTF	Typ. 40.0 % at 2.0 lp/mm	EVS 4343A: 44.1% at 2.0 lp/mm
		EVS 3643A: 44.5 % at 2.0 lp/mm

The EXPD 4343D, EXPD 3643D 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 4343D, EXPD 3643D 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	

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

The modified EXPD 4343D and EXPD 3643D detectors(K232753) are substantially equivalent to the currently marketed and predicate device (K192400) 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 4343D and EXPD 3643D 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.