DRTECH Corporation
% Mr. Dongwook Shin
Regulatory Affairs Responsible
Suite No.1, 1 Floor / Suite No.2, 3 Floor, 29
Dunchon-daero 541 beon-gil,
Jungwon-gu, Seongnam-si, Gyeonggi-do 13216
REPUBLIC OF KOREA

November 22, 2019

Re: K193031
Trade/Device Name: EXPD 4343P/ EXPD 3643P
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MQB
Dated: October 29, 2019
Received: October 30, 2019

Dear Mr. Dongwook Shin:

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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193031

Device Name
EXPD 4343P / EXPD 3643P

Indications for Use *(Describe)*
The EXPD 4343P / EXPD 3643P 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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Gyeonggi-do, Republic of Korea

510(k) Summary

[As required by 21 CFR 807.92]

K193031

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)]

11/15/2019

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

- Name of Sponsor: DRTECH Corporation
- Address: Suite No.1, 1 Floor / Suite No. 2, 3 Floor, 29, Dunchon-daero541 beon-gil, Jungwon-gu, Seongnam-si, Gyeonggi-do, Republic of Korea
- Contact Name: DONGWOOK, SHIN
- Telephone No.: + 82-31-779-7783
- Fax No.: + 82-31-779-7790
- Email Address : dwshin@drtech.co.kr
- Registration Number: 3005172103
- Name of Manufacturer: Same as Sponsor

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

- Trade Name: EXPD 4343P / EXPD 3643P
- 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)]

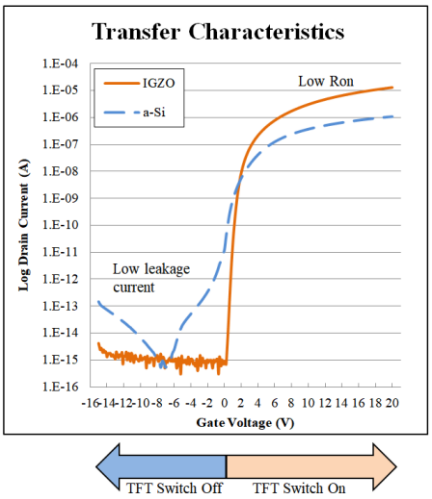
- 510(k) Number: K192400
- Applicant: DRTECH Corporation
- Trade Name: EVS 4343A / EVS 4343AG / EVS 3643A / EVS 3643AG
- Classification Name: Stationary X-ray System
- Classification Panel: Radiology
- Classification Regulation: 21 CFR 892.1680
- Product Code: MQB
- Device Class: II

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

<Modification>

Addition of EXPD 4343P / EXPD 3643P: 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.

IGZO is compound of indium(In)-gallium(Ga)-zinc(Zn)-oxygen(O) and this compound is utilized as semiconductor material of TFT. Semiconductor material is only different material between conventional amorphous silicon TFT, that utilizing silicon as semiconductor material, and amorphous IGZO TFT. As IGZO has less resistance and leakage current on TFT switch off status than conventional amorphous silicon TFT, resistance capacity delay time for signal output could be reduced compare to conventional amorphous silicon TFT and also, line noise could be reduced compare to conventional amorphous silicon TFT. Difference between amorphous IGZO and conventional amorphous silicon TFT is shown in below table and right figure.



Category	IGZO TFT	a-Si TFT
Active Layer (Semiconductor Material)	indium(In)-gallium(Ga)-zinc(Zn)-oxygen(O)	Silicon(Si):H
Crystal structure	Amorphous	Amorphous
On Resistance(Ron)	0.1~0.9MΩ	1~10MΩ
Leakage current (TFT switch off status)	$<10^{-15}$A	$<10^{-14}$A

The EXPD 4343P / EXPD 3643P is a 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 4343P / EXPD 3643P 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 x-ray generator, a necessary component for a complete diagnostic system, is not part of the device. The subject detector is supported by software, Econsole1 (cleared under K152172). The subject software is the same as the predicate.

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

The EXPD 4343P / EXPD 3643P 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 4343P / EXPD 3643P Detector is an indirect conversion device 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.
Comparisons with the predicate, devices show the technological characteristics of the EXPD 4343P / EXPD 3643P to be same to the predicate devices. EXPD 4343P / EXPD 3643P is functionally identical to the predicate devices.

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

Parameter		Subject Device	Predicate Device
510(K) Number		K193031	K192400
Manufacturer		DRTECH Corporation	DRTECH Corporation
Model Name		EXPD 4343P EXPD 3643P	EVS 4343A / EVS 4343AG EVS 3643A / EVS 3643AG
Classification Name		Stationary X-ray System	
Classification Panel		Radiology	
Classification Regulation		21 CFR 892.1680	
Product Code		MQB	
Device Class		Class II	
Intended Use		The EXPD 4343P / EXPD 3643P 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 EVS 4343A / EVS 4343AG / EVS 3643A / EVS 3643AG 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 4343P: Square Panel	EVS 4343A: Square Panel EVS 4343AG: Square Panel
		EXPD 3643P: Rectangular Panel	EVS 3643A: Rectangular Panel EVS 3643AG: Rectangular Panel
	Detector Size	EXPD 4343P: 17” X 17”	EVS 4343A: 17” X 17” EVS 4343AG: 17” X 17”
		EXPD 3643P: 13” X 17”	EVS 3643A: 13” X 17” EVS 3643AG: 13” X 17”

Parameter			Subject Device	Predicate Device
		Dimensions	EXPD 4343P: 460(W) x 483(L) x 15.5(H)	EVS 4343A: 460(W) x 483(L) x 15.5(H) EVS 4343AG: 460(W) x 483(L) x 15.5(H)
			EXPD 3643P: 460(W) × 409(L) × 15.5(H)	EVS 3643A: 460(W) × 409(L) × 15.5(H) EVS 3643AG: 460(W) × 409(L) × 15.5(H)
		Pixel Pitch	140μm	140μm
		Image Size	EXPD 4343P: 3,072 x 3,072	EVS 4343A: 3,072 x 3,072 EVS 4343AG: 3,072 x 3,072
			EXPD 3643P: 2,560 x 3,072	EVS 3643A: 2,560 x 3,072 EVS 3643AG: 2,560 x 3,072
Scintillator & TFT Materials			TFT –IGZO	TFT –amorphous Silicon
			EXPD 4343P / EXPD 3643P: CsI	EVS 4343A/EVS 3643A: CsI
				EVS 4343AG/ EVS 3643AG: GOS
Performance		DQE	EXPD 4343P: 50.0 % at 1.0 lp/mm	EVS 4343A: 52.9% at 1.0 lp/mm EVS 4343AG: 27.2 % at 1.0 lp/mm
			EXPD 3643P: 52.3 % at 1.0 lp/mm	EVS 3643A: 50.5 % at 1.0 lp/mm EVS 3643AG: 26.3 % at 1.0 lp/mm
		MTF	EXPD 4343P: 52.3 % at 2.0 lp/mm	EVS 4343A: 44.1 % at 2.0 lp/mm EVS 4343AG: 49.2 % at 2.0 lp/mm
			EXPD 3643P: 46.8 % at 2.0 lp/mm	EVS 3643A: 44.5 % at 2.0 lp/mm EVS 3643AG: 46.3 % 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
Component			PoE Adaptor Lan cables(2 ea) AC Power Cable Ethernet Connector Bracket	PoE Adaptor Lan cables(2 ea) AC Power Cable Ethernet Connector Bracket
Communication Interface			Wired: Ethernet	Wired: Ethernet

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

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

- Size

A few differences are as follows

- Performance (DQE and MTF)
- TFT Panel

There are no significant differences between the EXPD 4343P / EXPD 3643P 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.

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

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

Parameter	Modified Device	Predicate Device	Remark
DQE	EXPD 4343P: 50.0% at 1.0 lp/mm	EVS 4343A: 52.9 % at 1.0 lp/mm EVS 4343AG: 27.2 % at 1.0 lp/mm	
	EXPD 3643P: 52.3 % at 1.0 lp/mm	EVS 3643A: 50.5 % at 1.0 lp/mm EVS 3643AG: 26.3 % at 1.0 lp/mm	
MTF	EXPD 4343P: 52.3 % at 2.0 lp/mm	EVS 4343A: 44.1 % at 2.0 lp/mm EVS 4343AG: 49.2 % at 2.0 lp/mm	
	EXPD 3643P: 46.8 % at 2.0 lp/mm	EVS 3643A: 44.5 % at 2.0 lp/mm EVS 3643AG: 46.3 % at 2.0 lp/mm	

The EXPD 4343P / EXPD 3643P detector complies with the following international and FDA-recognized consensus standards:

Recognition No.	Standard No.	Title of Standard	Remark
19-4	ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)	
12-289	IEC 62220-1 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	
5-40	ISO 14971 Second edition 2007-03-01	Medical devices - Application of risk management to medical devices	
5-89	IEC 60601-1-6 Edition 3.1	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	
12-300	PS 3.1 - 3.20 (2016)	Digital Imaging and Communications in Medicine (DICOM) Set	
19-8	IEC 60601-1-2 Edition 4.0	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	
13-32	ANSI AAMI IEC 62304:2006	Medical device software - Software life cycle processes	

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

The modified EXPD 4343P / EXPD 3643P detector is substantially equivalent to the currently marketed and predicate device (EVS 4343A / EVS 4343AG / EVS 3643A / EVS 3643AG - 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/(R)2012 and A1:2012, IEC 60601-1-2:2014, ANSI AAMI IEC 62304:2006 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 4343P / EXPD 3643P meets the acceptance criteria and is 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.