November 22, 2019

DRTECH Corporation
% Shin Dongwook
Regulatory Affairs Responsible
Suite No.1, 1 Floor / Suite No.2, 3 Floor, 29
Dunchon-daero541 beon-gil,
Jungwon-gu, Seongam-si, 13216
REPUBLIC OF KOREA

Re: K193017
Trade/Device Name: EVS 4343W / EVS 4343WG / EVS 4343WP / EVS 3643W / EVS 3643WG / EVS 3643WP
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MQB
Dated: October 28, 2019
Received: October 29, 2019

Dear Shin Dongwook:

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,

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)*
K193017

Device Name
EVS 4343W / EVS 4343WG / EVS 4343WP / EVS 3643W / EVS 3643WG / EVS 3643WP

Indications for Use *(Describe)*
The EVS 4343W / EVS 4343WG / EVS 4343WP / EVS 3643W / EVS 3643WG / EVS 3643WP 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)

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Gyeonggi-do, Republic of Korea

510(k) Summary

[As required by 21 CFR 807.92]

K193017

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)]

11/22/2019

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: EVS 4343W / EVS 4343WG / EVS 4343WP
  EVS 3643W / EVS 3643WG / EVS 3643WP
- 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: K162552
- Applicant: DRTECH Corporation
- Trade Name: EVS 3643 / EVS 3643G
- Classification Name: Stationary X-ray System
- Classification Panel: Radiology
- Classification Regulation: 21 CFR 892.1680
- Product Code: MQB
- Device Class: II

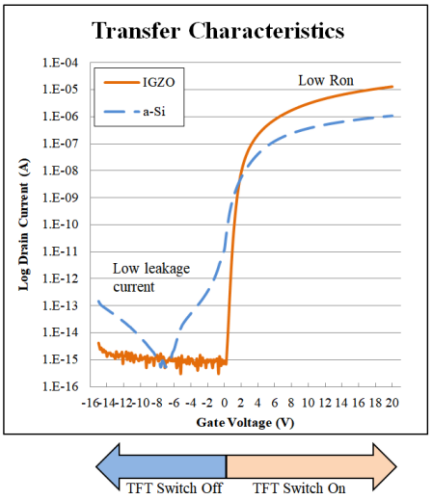
5. Description of the Modified Device [21 CFR 807.92(a) (4)]

<Modification>

Addition of EVS 4343W / EVS 4343WG / EVS 4343WP / EVS 3643W / EVS 3643WG / EVS 3643WP: The differences between the subject devices and the predicate devices are the size and the performance (MTF, DQE) of their detectors. In case of EVS 3643WP and EVS 4343WP, the TFT type was changed from amorphous Silicon to amorphous IGZO. These detectors differ in terms of the layers of their scintillators and TFT Type as shown in the following table:

Model Name	Scintillator layer	Photodiode	TFT
EVS 4343W	CsI (Cesium Iodide)	a-Si(PIN diode)	amorphous Silicon
EVS 4343WG	GOS (Gadolinium Oxysulfide)	a-Si(PIN diode)	amorphous Silicon
EVS 3643W	CsI (Cesium Iodide)	a-Si(PIN diode)	amorphous Silicon
EVS 3643WG	GOS (Gadolinium Oxysulfide)	a-Si(PIN diode)	amorphous Silicon
EVS 4343WP	CsI (Cesium Iodide)	a-Si(PIN diode)	amorphous IGZO
EVS 3643WP	CsI (Cesium Iodide)	a-Si(PIN diode)	amorphous IGZO

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

In wired mode, Predicate devices used SSU or functional cable with Lan cable, however, subject devices use USB Type C to Ethernet and Lan cable.

Optional components were removed such as generator interface cable, USB switch box and hand switch, USB cable and X-ray cable compared to predicated devices components.

The x-ray generator, a necessary component for a complete diagnostic system, is not part of the device. The EVS 4343W / EVS 4343WG / EVS 4343WP / EVS 3643W / EVS 3643WG / EVS 3643WP detectors are compatible with the Econsole1 software(Cleared under K152172). The subject software is the same as the predicate.

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

The EVS 4343W / EVS 4343WG / EVS 4343WP / EVS 3643W / EVS 3643WG / EVS 3643WP 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 EVS 4343W / EVS 4343WG / EVS 4343WP / EVS 3643W / EVS 3643WG / EVS 3643WP 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 EVS 4343W / EVS 4343WG / EVS 4343WP / EVS 3643W / EVS 3643WG / EVS 3643WP to be same to the predicate devices. The EVS 4343W / EVS 4343WG / EVS 4343WP / EVS 3643W / EVS 3643WG / EVS 3643WP is functionally identical to the predicate devices.

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

Parameter		Subject Device	Predicate Device
510(K) Number		K193017	K162552
Manufacturer		DRTECH Corporation	DRTECH Corporation
Model Name		EVS 4343W / EVS 4343WG / EVS 4343WP / EVS 3643W / EVS 3643WG / EVS 3643WP	EVS 3643 / EVS 3643G
Classification Name		Stationary X-ray System	
Classification Panel		Radiology	
Classification Regulation		21 CFR 892.1680	
Product Code		MQB	
Device Class		Class II	
Intended Use		EVS 4343W / EVS 4343WG / EVS 4343WP / EVS 3643W / EVS 3643WG / EVS 3643WP 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.	EVS 3643, EVS 3643G 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	EVS 4343W: Square Panel EVS 4343WG: Square Panel EVS 4343WP: Square Panel	Rectangular Panel
		EVS 3643W: Rectangular Panel EVS 3643WG: Rectangular Panel EVS 3643WP: Rectangular Panel	
	Detector Size	EVS 4343W: 17” X 17” EVS 4343WG: 17” X 17” EVS 4343WP: 17” X 17”	13” X 17”
		EVS 3643W: 13” X 17” EVS 3643WG: 13” X 17” EVS 3643WP: 13” X 17”	
	Dimensions	EVS 4343W: 460(W) x 460(L) x 15(H) EVS 4343WG: 460(W) x 460(L) x 15(H) EVS 4343WP: 460(W) x 460(L) x 15(H)	460(W) x 380(L) x 14.7(H)
		EVS 3643W: 460(W) × 386(L) × 15(H) EVS 3643WG: 460(W) × 386(L) × 15(H) EVS 3643WP: 460(W) × 386(L) × 15(H)	

Parameter		Subject Device	Predicate Device
	Pixel Pitch	140μm	140μm
	Image Size	EVS 4343W: 3,072 x 3,072 EVS 4343WG: 3,072 x 3,072 EVS 4343WP: 3,072 x 3,072	2,560 x 3,072
		EVS 3643W: 2,560 x 3,072 EVS 3643WG: 2,560 x 3,072 EVS 3643WP: 2,560 x 3,072	
Materials Scintillator		EVS 4343W: CsI EVS 3643W: CsI EVS 4343WP: CsI EVS 3643WP: CsI	EVS 3643: CsI
		EVS 4343WG: GOS EVS 3643WG: GOS	EVS 3643G: GOS
TFT		EVS 4343W: amorphous Silicon EVS 3643W: amorphous Silicon EVS 4343WP: amorphous IGZO EVS 3643WP: amorphous IGZO EVS 4343WG: amorphous Silicon EVS 3643WG: amorphous Silicon	EVS 3643: amorphous Silicon EVS 3643G: amorphous Silicon
Performance	DQE	EVS 4343W: 52.8% at 1.0 lp/mm EVS 3643W: 53.3% at 1.0 lp/mm EVS 4343WP: 50.0% at 1.0 lp/mm EVS 3643WP: 53.1% at 1.0 lp/mm	EVS 3643: 55.3 % at 1.0 lp/mm
		EVS 4343WG: 25.1% at 1.0 lp/mm EVS 3643WG: 25.9% at 1.0 lp/mm	EVS 3643G: 23.6 % at 1.0 lp/mm
	MTF	EVS 4343W: 50.0% at 2.0 lp/mm EVS 3643W: 42.5% at 2.0 lp/mm EVS 4343WP: 48.4% at 2.0 lp/mm EVS 3643WP: 42.9% at 2.0 lp/mm	EVS 3643: 37.8% at 2.0 lp/mm
		EVS 4343WG: 50.1% at 2.0 lp/mm EVS 3643WG: 47.8% at 2.0 lp/mm	EVS 3643G: 34 % 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
Communication Method		Wire	Wire
		Wireless • IEEE 802.11a//g/n (2.4 GHz / 5 GHz) • Security: WEP/WPA/WPA2	Wireless • IEEE 802.11a//g/n (2.4 GHz / 5 GHz) • Security: WEP/WPA/WPA2

When compared to the predicate devices (K162552), the EVS 4343W / EVS 4343WG / EVS 4343WP / EVS 3643W / EVS 3643WG / EVS 3643WP presented in this submission have the same:

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

A few differences are as follows

- Size
- TFT Type
- Performance (DQE and MTF)
- Components

There are no significant differences between the EVS 4343W / EVS 4343WG / EVS 4343WP / EVS 3643W / EVS 3643WG / EVS 3643WP 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
DQE	EVS 4343W: 52.8% at 1.0 lp/mm EVS 3643W: 53.3% at 1.0 lp/mm EVS 4343WP: 50.0% at 1.0 lp/mm EVS 3643WP: 53.1% at 1.0 lp/mm	EVS 3643: 55.3 % at 1.0 lp/mm
	EVS 4343WG: 25.1% at 1.0 lp/mm EVS 3643WG: 25.9% at 1.0 lp/mm	EVS 3643G: 23.6 % at 1.0 lp/mm
MTF	EVS 4343W: 50.0% at 2.0 lp/mm EVS 3643W: 42.5% at 2.0 lp/mm EVS 4343WP: 48.4% at 2.0 lp/mm EVS 3643WP: 42.9% at 2.0 lp/mm	EVS 3643: 37.8% at 2.0 lp/mm
	EVS 4343WG: 50.1% at 2.0 lp/mm EVS 3643WG: 47.8% at 2.0 lp/mm	EVS 3643G: 34 % at 2.0 lp/mm

The EVS 4343W / EVS 4343WG / EVS 4343WP / EVS 3643W / EVS 3643WG / EVS 3643WP 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	

The software of EVS 4343W / EVS 4343WG / EVS 4343WP / EVS 3643W / EVS 3643WG / EVS 3643WP comply with the following FDA Guidance documents:

“Content of Premarket Submissions for Management of Cybersecurity in Medical Devices” and

“Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices”

A single blind clinical image evaluation according to CDRH's “Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices” was conducted as EVS 4343WP, EVS 3643WP utilized IGZO TFT that is different from predicate device. In this evaluation, 8 positions of body parts (Chest PA, C-spine AP, C-spine LAT, L-spine AP, L-spine LAT, Shoulder AP, Shoulder LAT,

Extremities) were selected to compare image performance between EVS 4343WP, EVS 3643WP and EVS 3643(K162552). Through this clinical image evaluation, it is indicated that there is no significant difference of image performance between EVS 4343WP, EVS 3643WP and EVS 3643 as difference in the score is within one standard deviation.
Thus, this clinical image evaluation confirmed that the subject x-ray detectors(EVS 4343WP, EVS 3643WP) provide images of equivalent diagnostic capability to the predicate device (EVS 3643 - K162552).

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

The modified EVS 4343W / EVS 4343WG / EVS 4343WP / EVS 3643W / EVS 3643WG / EVS 3643WP detector is substantially equivalent to the currently marketed and predicate device (EVS 3643 / EVS 3643G, K162552) in terms of fundamental scientific technology, indications for use, and safety and effectiveness.

Additionally, Substantial equivalence was demonstrated through the non-clinical and 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, IEC 62220-1-1 and clinical image evaluation 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 EVS 4343W / EVS 4343WG / EVS 4343WP / EVS 3643W / EVS 3643WG / EVS 3643WP 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.