DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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December 2, 2016

DRTECH Corporation
% Mr. Choul-Woo Shin
Suite no. 2, 3rd floor, 29, Dunchon-daero 541 beon-gil
Jungwon-gu, Seongnam-si, Gyeonggi-do, 13230
REPUBLIC OF KOREA

Re: K162552
Trade/Device Name: EVS 3643, EVS 3643G
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: October 31, 2016
Received: November 2, 2016

Dear Mr. Choul-Woo 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162552

Device Name
EVS 3643, EVS 3643G

Indications for Use *(Describe)*
The EVS 3643 and 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.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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)]

10/28/2016

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

- Name of Sponsor: DRTECH Corporation
- Address: Suit No. 2, 3 Floor, 29, Dunchon-daero541 beon-gil, Jungwon-gu, Seongnam-si, Gyeonggi-do, 13230, Republic of Korea
- Contact Name: Choul-Woo Shin
- Telephone No.: + 82-31-779-7783
- Fax No.: + 82-31-779-7790
- Email Address : cwshin@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 3643, EVS 3643G
- 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
- 501(k) Number: K162552

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

Parameter	Predicate Device	
• 510(k) Number:	K151942	K150766
• Applicant:	DRTECH Corporation	Carestream Health, Inc.
• Trade Name:	EVS 3643	Carestream DRX-1 System w/ DRX Plus Detectors
• 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>

- A wireless charging function and accessories (EVS-WPCS) were added to EVS 3643(G) for wireless charging.
- Addition of EVS 3643G: This is to notify that modified EVS 3643 / EVS 3643G are same Hardware, Software and components. But scintillator layer are different. Scintillator is a phosphor that produces scintillations.

Model Name	Scintillator layer
EVS 3643	CsI (Cesium Iodide)
EVS 3643G	GoS (Gadolinium Oxysulfide)

The EVS 3643(G) is a wired/wireless 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. EVS 3643(G) 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.

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

The intended use has not changed as a result of the modification and is as follows:

The EVS 3643 and 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.

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

The EVS 3643(G) 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 3643(G) to be same to the predicate devices. The EVS 3643(G) is functionally identical to the predicate devices.

The subject device integrates with X-ray system through three modes such as Auto Trigger mode (AT), Sync. Trigger mode and USB SW mode. The Auto Trigger Mode (AT) is available for acquiring images without any connection to X-ray generator. A generator interface cable is not required. The Sync. Trigger mode is the most common and recommended exposure mode at B2B scopes. User can achieve the high quality images with Sync. Tigger Mode. The USB SW Mode is the most common and recommended exposure mode at a retrofit scope. User can achieve high quality images with USB SW Mode.

8. Hardware and Software Requirements

- X-ray System Requirement

Contents		Requirements	
Generator	Power frequency	30kHz ~ 240kHz	
	KV	40kVp ~ 150kVp	
	mA Range	10mA ~ 1000mA	
	Exposure Time	0.001~10sec	
	mAs Range	0.1~1000mAs	
	Accuracy	± 5%	
Bucky	Operating Type	moving	Stepping Motor
			Spring
			CAM Motor type
		Static(Fixed)	
	Trey size (mm)	386 x 460 x 15 or higher	
Grid	Ratio	5:1, 6:1, 8:1, 10:1, 12:1, 15:1	
	Line	85 ~ 215 Line	
	SID	100 ~ 180 cm	

* The EVS 3643(G) detector is not compatible with trays that are less than 386 mm x 460 mm x 15 mm.

- Software Requirement

The EVS 3643(G) detector is compatible with Econsole1 (K152172).

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

Parameter	Subject Device	Predicate Device		Re mark
510(K) Number	K162552	K151942	K150766	-
Manufacturer	DRTECH Corporation	DRTECH Corporation	Carestream Health, Inc.	-
Model Name	EVS 3643, EVS 3643G	EVS 3643	Carestream DRX-1 System w/ DRX Plus Detectors	-
Classification Name	Stationary X-ray System			same
Classification Panel	Radiology			same
Classification Regulation	21 CFR 892.1680			same
Product Code	MQB			same
Device Class	Class II			same
Intended Use	The EVS 3643, EVS 3643G Digital X-ray detector is indicated for digital imaging solution designed for providing general	The EVS 3643 Digital X-ray detector is indicated for digital imaging solution designed for providing general	The device is intended to capture for display radiographic images of human anatomy	same

		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	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	including both pediatric and adult patients. The device is intended for use in general projection radiographic applications wherever conventional screen-film systems or CR systems may be used. Excluded from the indications for use are mammography, fluoroscopy, and angiography applications.	
Design	Panel Shape	Rectangular Panel	Rectangular Panel	Rectangular Panel	same
	Detector Size	13” X 17”	13” X 17”	13” X 17”	same
	Pixel Pitch	140µm	140µm	139µm	same
Materials Scintillator		TFT –amorphous Silicon	TFT –amorphous Silicon	TFT –amorphous Silicon	same
		EVS 3643: CsI	EVS 3643: CsI	GOS	same
		EVS 3643G: GOS			
Performance	DQE	EVS 3643: 36.8 % at 1 lp/mm 25.56 % at 3 lp/mm	36.8 % at 1 lp/mm 25.56 % at 3 lp/mm	29.7 % at 1 lp/mm 5.0 % at 3 lp/mm	same
		EVS 3643G: 34.6 % at 1 lp/mm 5 % at 3 lp/mm			same
	MTF	EVS 3643: 37.8 % at 2 lp/mm	37.8 % at 2 lp/mm	17.4% at 2 lp/mm	same
		EVS 3643G: 34 % at 2 lp/mm			same
	Resolution	3.5 lp/mm	3.5 lp/mm	3.5 lp/mm	same
	Wireless Charging	available	non-available	non-available	different
Anatomical Sites		General Radiography	General Radiography	General Radiography	same
Power Supply		100~240V~, 50/60 Hz	100~240V~, 50/60 Hz	100~240V~, 50/60 Hz	same
Communication		Wire	Wire	-	same

Method	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	-	
Exposure Mode	USB SW Mode Sync Trigger Mode Auto Trigger Mode	USB SW Mode Sync Trigger Mode Auto Trigger Mode	-	same

When compared to the predicate devices (K151942 and K150766), the EVS 3643(G) presented in this submission has the same:

- Intended Use
- Technological characteristics
- Operating principle
- Materials Scintillator
- Design features
- Performance (DQE, MTF, Resolution)

A few differences are as follows

- Performance (Wireless charging)

There are no significant differences between the EVS 3643(G) and the predicate devices 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.

10. 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 higher the predicate device as following table:

Parameter	Modified Device	Predicate Device		Remark
		K151942	K150766	
DQE	EVS 3643: 36.8 % at 1 lp/mm 25.56% at 3 lp/mm EVS 3643G: 34.6 % at 1 lp/mm 5 % at 3 lp/mm	36.8 % at 1 lp/mm 25.56 % at 3 lp/mm	29.7 % at 1 lp/mm 5.0 % at 3 lp/mm	Same
MTF	EVS 3643: 35 % at 2 lp/mm EVS 3643G: 30 % at 2 lp/mm	35 % at 2.0 lp/mm	17.4% at 2.0 lp/mm	Same

The EVS 3643(G) complies with the following international and FDA-recognized consensus standards:

AAMI ANSI ES60601-1:	Medical Electrical Equipment -- Part 1: General Requirements for Basic Safety And Essential Performance (IEC 60601- 1:2005, Mod)
IEC 60601-1-2:	Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance – Collateral Standard: Electromagnetic Compatibility - Requirements And Tests (Edition 3)
ISO 14971:	Medical Devices - Application of Risk Management to Medical Devices. (General I (QS/RM))
IEC 62220-1:	Medical electrical equipment - Characteristics of digital X-ray imaging devices - Part 1: Determination of the detective quantum efficiency
NEMA PS 3.1 - 3.20:	Digital Imaging and Communications in Medicine (DICOM) Set

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

A single-blinded concurrence study according to CDRH's Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices was conducted, and the study confirmed that the new x-ray detectors EVS 3643G provide images of equivalent diagnostic capability to the predicate devices (K151942 and K150766) and its results demonstrate substantial equivalence.

Clinical images were provided; these images were not necessary to establish substantial equivalence based on the modifications to the device (note X-ray detector technology that is identical to the predicate device) but they provide further evidence in addition to the laboratory performance data to show that the subject device works as intended.

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

The modified EVS 3643(G) is substantially equivalent to the currently marketed and predicate device (EVS 3643(K151942) and Carestream DRX-1 System w/ DRX Plus Detectors(K150766)) in terms of design features, 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, IEC60601-1, IEC 60601-1-2, IEC62220-1 and IEC 62133 and the clinical test, 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 EVS 3643(G) meets the acceptance criteria and is adequate for this intended use. The comparison of technological characteristics, non-clinical performance data, safety testing, and clinical image concurrence data demonstrates that the device is as safe, as effective, and performs as well or better than the predicate devices.