**DEPARTMENT OF HEALTH & HUMAN SERVICES** Public Health Service

Food and Drug Administration
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DRTech Corporation
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Jungwon-gu, Seongnam-si, Gyeonggi-do 462-807
REPUBLIC OF KOREA

October 21, 2015

Re: K151942
Trade/Device Name: EVS 3643
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: September 2, 2015
Received: September 9, 2015

Dear Mr. 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,

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)*
K151942

Device Name
EVS 3643

Indications for Use *(Describe)*
The EVS 3643 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)]**

06/01/2014

**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,<br>Jungwon-gu, Seongnam-si, Gyeonggi-do 462-807<br>Republic of Korea |
| Contact Name: | Choul-Woo Shin<br>Telephone #: +82-31-784-8856<br>Fax #: +82-31-784-8899<br>Email: 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)]**

| | |
|---|---|
| Model Name: | EVS 3643 |
| Common Name: | Digital Flat Panel X-ray Detector |
| Regulation Name: | Stationary x-ray system |
| Regulation Number: | 21 CFR 892.1680 |
| Product Code: | MQB |
| Device Class: | 2 |
| Review Panel: | Radiology |

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

| | |
|---|---|
| 510(k) Number: | K142475 |
| Applicant: | DRTECH Corporation. |
| Model Name: | EVS 4343 |
| Common Name: | Digital Flat Panel X-ray Detector |
| Regulation Name: | Stationary x-ray system |
| Regulation Number: | 21 CFR 892.1680 |
| Product Code: | MQB |
| Device Class: | 2 |

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

The EVS 3643 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 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.
EVS 3643 consists of main components such as SSU, USB Switch Box, Battery Pack, Battery charger and other accessories (Tether Interface Cable, Hand Switch, Generator Interface Cable, LAN Cable, Interface cable, AC Power Code).
EVS 3643 should be integrated with an operating PC and an X-Ray generator.

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

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

**8. Substantial Equivalence [21 CFR 807.92(b) (1) and 807.92]**

**EVS 3643 is a series of the predicate device EVS 4343. The size of the detector, power supply to the detector and the wireless connection are improved.**

When compared to the predicate devices (K142475), the EVS 3643 presented in this submission has the same of the followings:

- Intended Use
- Technological characteristics
- Design features
- Communication Method
- Scintillator Materials

The two devices share the similar performance as the following:

- Performance (MTF)
- Performance (DQE)
- Resolution
- Software version

However, the size of the predicate device's detector is 17" X 17" whereas that of EVS 3643 is 14" X 17". Also, the predicate device connects the detector to the SSU through a wire for power supply and data communication whereas the EVS 3643 is also capable of using the battery inside the detector and wireless communication of top of the method the predicate device uses.

Also, there is a change in the version of the software due to the different size of the detector, but there is no change in the function of the software.

In summary, after comparing EVS 3643 and the predicate device, no significant difference was observed. Also, the main comparison items including the intended use and technological characteristics were highly similar or the same. Therefore, EVS 3643 is substantially equivalent to the predicate device.

| Parameter | Subject Device | Predicate Device |
|---|---|---|
| 510(k) Number | Unknown | K142475 |
| Model Name | EVS 3643 | EVS 4343 |
| Manufacturer | DRTECH Corporation | |
| Common Name | Digital Flat Panel X-ray Detector | |
| Regulation Name | Stationary x-ray system | |
| Classification Panel | Radiology | |
| Classification Regulation | 21 CFR 892.1680 | |
| Product Code | MQB | |
| Device Class | Class II | |
| Intended Use | The EVS 3643 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 4343 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 |
| Panel Shape | Rectangular Panel | Square Panel |
| Detector Size | 13" X 17" | 17" X 17" |
| Pixel Pitch | 140μm | 140μm |

| | | |
|---|---|---|
| Scintillator | TFT –amorphous Silicon<br>CsI (Indirect) | TFT –amorphous Silicon<br>CsI (Indirect) |
| Communication Method | Wire | Wire |
| | Wireless<br>• IEEE 802.11a//g/n (2.4 GHz / 5 GHz)<br>• Security: WEP/WPA/WPA2 | Wireless<br>• IEEE 802.11a//g/n (2.4 GHz / 5 GHz)<br>• Security: WEP/WPA/WPA2 |
| DQE | 50% (at 1.0 Lp/mm) | 52% (at 1.0 Lp/mm) |
| MTF | 35% (at 2.0 Lp/mm) | 36.6% (at 2.0 Lp/mm) |
| Resolution | 3.5 LP/mm | 3.6 LP/mm |
| Anatomical Sites | General Radiography | General Radiography |
| Exposure Mode | USB SW Mode<br>Sync Trigger Mode<br>Auto Trigger Mode | USB SW Mode<br>Sync Trigger Mode<br>Auto Trigger Mode |
| Power Supply | 100~240V, 50/60 Hz | 100~240V, 50/60 Hz |

**9. Summary of Non-Clinical Data**

A comparison test was conducted between the EVS3643 and the predicate device (K142475) on the items such as DQE, MTF and spatial resolution.

These detectors comply with the following international and FDA-recognized consensus standards:

| | |
|---|---|
| IEC 60601-1: | Medical Electrical Equipment -- Part 1: General Requirements For Basic Safety And Essential Performance |
| 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 |
| IEC 62220-1: | Medical electrical equipment - Characteristics of digital X-ray imaging devices - Part 1: Determination of the detective quantum efficiency |
| IEC 62133: | Secondary Cells And Batteries Containing Alkaline Or Other Non-Acid Electrolytes•Safety Requirements For Portable Sealed Secondary Cells, And For Batteries Made From Them, For Use In Portable Applications [Including: Corrigendum 1 (2013) |
| EN 300 328 1.8.1: | Electromagnetic compatibility and Radio spectrum Matters (ERM); Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques; Harmonized EN |

| | |
|---|---|
| | covering the essential requirements of article 3.2 of the R&TTE Directive |
| EN 301 893 1.7.1: | Broadband Radio Access Networks (BRAN); 5 GHz high performance RLAN; Harmonized EN covering the essential requirements of article 3.2 of the R&TTE Directive |

## 10. Summary of Clinical Data

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 3643 provide images of equivalent diagnostic capability to the predicate devices (K142475) 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.

## 11. Conclusion [21 CFR 807.92(b) (3)]

The EVS 3643 is substantially equivalent to the currently marketed and predicate devices (K142475) 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 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 the predicate devices.