January 26, 2023

DRTECH Corporation
Choul-Woo Shin
Vice President
Suite No.1, 1 Floor / Suite No.2, 3 Floor, 29,
Dunchon-daero541 beon-gil,
Jungwon-gu, Seongam-si, Gyeonggi-do 13216
REPUBLIC OF KOREA

Re: K192400
Trade/Device Name: EVS 4343A, EVS 4343AG, EVS 3643A, EVS 3643AG
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MQB

Dear Choul-Woo Shin:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated October 3, 2019. Specifically, FDA is updating this SE Letter as an administrative correction to update the 510(k) Summary document, where the dimensions of several detector models were previously misstated as "13" instead of "14".

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Dr. Lu Jiang, OHT8: Office of Radiological Health, 240-402-5779, lu.jiang@fda.hhs.gov.

Sincerely,

Laurel Burk, Ph.D.
Director
DHT8B: Division of Radiological Imaging Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

October 3, 2019

DRTECH Corporation
% Choul-Woo Shin
Vice President
Suite No.1, 1 Floor / Suite No.2, 3 Floor, 29,
Dunchon-daero541 beon-gil,
Jungwon-gu, Seongam-si, Gyeonggi-do 13216
REPUBLIC OF KOREA

Re: K192400
Trade/Device Name: EVS 4343A, EVS 4343AG, EVS 3643A, EVS 3643AG
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MQB
Dated: August 27, 2019
Received: September 3, 2019

Dear 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. 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)*
K192400

Device Name
EVS 4343A / EVS 4343AG / EVS 3643A / EVS 3643AG

Indications for Use *(Describe)*
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.

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.**

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

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

DRTECH Corporation
Suite No.1, 1 Floor / Suite No. 2, 3 Floor, 29,
Dunchon-Daero 541beon-gil, Jungwon-gu, Seongnam-si,
Gyeonggi-do, Republic of Korea

# 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)]

08/27/2019

## 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: Choul-Woo 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 4343A / EVS 4343AG / EVS 3643A / EVS 3643AG
- 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: K162555
- Applicant: DRTECH Corporation
- Trade Name: EVS 4343 / EVS 4343G
- 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 4343A / EVS 4343AG / EVS 3643A / EVS 3643AG: The differences between the subject devices and the predicate devices are adaptor, cable type and performance (MTF & DQE). Predicate devices used tether cable, Lan cable and SSU, however, subject devices use 2 Lan cables and PoE Adaptor. In case of EVS 3643A and EVS 3643AG, the size is smaller than EVS 4343 and EVS 4343G.

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

The EVS 4343A / EVS 4343AG / EVS 3643A / EVS 3643AG 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. EVS 4343A / EVS 4343AG / EVS 3643A / EVS 3643AG 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 been changed as a result of the modification and is as follows:

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.

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

The EVS 4343A / EVS 4343AG / EVS 3643A / EVS 3643AG 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 4343A / EVS 4343AG / EVS 3643A / EVS 3643AG to be same to the predicate devices. EVS 4343A / EVS 4343AG / EVS 3643A / EVS 3643AG is functionally identical to the predicate devices.

| 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) | |
| | Tray size (mm) | 460 mm x 483 mm x 15.5 mm or higher | |
| Grid | Ratio | 5:1, 6:1, 8:1, 10:1, 12:1, 15:1 | |
| | Line | 85 ~ 215 Line | |
| | SID | 100 ~ 180 cm | |

**8. Hardware and Software Requirements**

- X-ray System Requirement

* The EVS 4343A / EVS 4343AG / EVS 3643A / EVS 3643AG detector is not compatible with trays that are less than 460 mm x 483 mm x 15.5 mm.

- Software Requirement

The EVS 4343A / EVS 4343AG / EVS 3643A / EVS 3643AG detector is compatible with Econsole1 (K152172).

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

| Parameter | | Subject Device | Predicate Device |
|---|---|---|---|
| 510(K) Number | | Unknown | K162555 |
| Manufacturer | | DRTECH Corporation | DRTECH Corporation |
| Model Name | | EVS 4343A / EVS 4343AG<br>EVS 3643A / EVS 3643AG | EVS 4343 / EVS 4343G |
| 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 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 | 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 | EVS 4343A: Square Panel<br>EVS 4343AG: Square Panel | Square Panel |
| | | EVS 3643A: Rectangular Panel<br>EVS 3643AG: Rectangular Panel | |
| | Detector Size | EVS 4343A: 17” X 17”<br>EVS 4343AG: 17” X 17” | 17” X 17” |
| | | EVS 3643A: 14” X 17”<br>EVS 3643AG: 14” X 17” | |
| | Dimensions | EVS 4343A:<br>460(W) x 483(L) x 15.5(H)<br>EVS 4343AG:<br>460(W) x 483(L) x 15.5(H) | 460(W) x 460(L) x 15(H) |
| | | EVS 3643A:<br>460(W) × 409(L) × 15.5(H)<br>EVS 3643AG:<br>460(W) × 409(L) × 15.5(H) | |
| | Pixel Pitch | 140μm | 140μm |
| | Image Size | EVS 4343A: 3,072 x 3,072<br>EVS 4343AG: 3,072 x 3,072 | 3,072 x 3,072 |
| | | EVS 3643A: 2,560 x 3,072<br>EVS 3643AG: 2,560 x 3,072 | |
| Materials Scintillator | | TFT –amorphous Silicon | TFT –amorphous Silicon |
| | | EVS 4343A/EVS 3643A: CsI | EVS 4343: CsI |
| | | EVS 4343AG/ EVS 3643AG: GOS | EVS 4343G: GOS |
| Performance | DQE | EVS 4343A: 52.9% at 1.0 lp/mm<br>EVS 3643A: 50.5 % at 1.0 lp/mm | EVS 4343: 43.9 % at 1.0 lp/mm |
| | | EVS 4343AG: 27.2 % at 1.0 lp/mm | EVS 4343G: 23.6 % at 1.0 lp/mm |

| | | | |
|---|---|---|---|
| | | EVS 3643AG: 26.3 % at 1.0 lp/mm | |
| | MTF | EVS 4343A: 44.1 % at 2.0 lp/mm<br>EVS 3643A: 44.5 % at 2.0 lp/mm | EVS 4343: 37.7 % at 2.0 lp/mm |
| | | EVS 4343AG: 49.2 % at 2.0 lp/mm<br>EVS 3643AG: 46.3 % at 2.0 lp/mm | EVS 4343G: 34.0 % 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<br>Lan cables(2 ea)<br>AC Power Cable<br>Ethernet Connector Bracket | EVS-SSU01<br>Lan cable<br>Tether cable<br>AC Power Cable<br>USB switch box<br>Hand switch<br>Generator interface cable<br>Interface cable |
| Communication Interface | | Wired: Ethernet | Wired: Ethernet |

When compared to the predicate devices (K162555), the EVS 4343A / EVS 4343AG / EVS 3643A / EVS 3643AG presented in this submission have the same:

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

A few differences are as follows

- Adaptor / cable type
- Components
- Size
- Performance (DQE and MTF)

There are no significant differences between the EVS 4343A / EVS 4343AG / EVS 3643A / EVS 3643AG 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 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 | EVS 4343A: 52.9% at 1.0 lp/mm<br>EVS 3643A: 50.5 % at 1.0 lp/mm | EVS 4343: 43.9 % at 1.0 lp/mm | |
| | EVS 4343AG: 27.2 % at 1.0 lp/mm<br>EVS 3643AG: 26.3 % at 1.0 lp/mm | EVS 4343G: 23.6 % at 1.0 lp/mm | |
| MTF | EVS 4343A: 44.1 % at 2.0 lp/mm<br>EVS 3643A: 44.5 % at 2.0 lp/mm | EVS 4343: 37.7 % at 2.0 lp/mm | |
| | EVS 4343AG: 49.2 % at 2.0 lp/mm<br>EVS 3643AG: 46.3 % at 2.0 lp/mm | EVS 4343G: 34.0 % at 2.0 lp/mm | |

The EVS 4343A / EVS 4343AG / EVS 3643A / EVS 3643AG 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 | |

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

The modified EVS 4343A / EVS 4343AG / EVS 3643A / EVS 3643AG detector is substantially equivalent to the currently marketed and predicate device (EVS 4343(G), K162555) 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 EVS 4343A / EVS 4343AG / EVS 3643A / EVS 3643AG 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.