March 19, 2025

DRTECH Corporation
% Juhee Lee
Official Correspondent
Suite No.1, 2 Floor / Suite No.2, 3 Floor, 29,
Dunchon-daero 541beon-gil, Jungwon-gu, Seongnam-si
Gyeonggi-do, 13216
SOUTH KOREA

Re: K243443
Trade/Device Name: Expd 4343n1; Expd 4343n; Expd 4343u1; Expd 4343nu; Expd 4343np; Expd 3643n1; Expd 3643n; Expd 3643u1; Expd 3643nu; Expd 3643np
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary X-Ray System
Regulatory Class: Class II
Product Code: MQB
Dated: November 12, 2024
Received: February 19, 2025

Dear Juhee Lee:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Gabriela M. Rodal -S Digitally signed by Gabriela M. Rodal -S for

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243443

Device Name

EXPD 4343N1;
EXPD 4343N;
EXPD 4343U1;
EXPD 4343NU;
EXPD 4343NP;
EXPD 3643N1;
EXPD 3643N;
EXPD 3643U1;
EXPD 3643NU;
EXPD 3643NP

Indications for Use *(Describe)*

The Digital X-ray detector, EXPD-N Series, is designed for use in digital imaging solutions for general radiographic diagnosis of human anatomy. This device is intended for use in all general diagnostic procedures, replacing film or screen-based radiographic systems for both adult and paediatric patients.
It is not intended for use in mammography.

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, 2 Floor/ Suite No. 2, 3 Floor, 29,
Dunchon-Daero 541beon-gil, Jungwon-gu, Seognam-si,
Gyeonggi-do, 13216, Republic of Korea

510(k) Summary
(K243443)

These 510(k) summaries of safety and effectiveness information is prepared in accordance with 21 CFR 807.92.

1. Date Prepared [21 CFR 807.92(a) (1)]

March 19, 2025

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

- **Company Name:** DRTECH Corporation
- **Address:** Suite No. 1, 2 Floor/ Suite No. 2, 3 Floor, 29, Dunchon-Daero 541beon-gil, Jungwon-gu, Seognam-si, Gyeonggi-do, 13216, Republic of Korea
- **Contact Person:** Juhee Lee
- **Phone:** + 82-31-779-7742
- **Fax:** +82-31-779-7790
- **Email:** drtechra@drtech.com

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

- **Trade/ Device Name:** EXPD 4343N1, EXPD 4343N, EXPD 4343U1, EXPD 4343NU, EXPD 4343NP, EXPD 3643N1, EXPD 3643N, EXPD 3643U1, EXPD 3643NU, EXPD 3643NP
- **Common Name:** Digital Flat Panel X-ray Detector
- **Classification Name:** Stationary X-ray System
- **Classification Panel:** Radiology
- **Product Code:** MQB
- **Regulation Number:** 21 CFR 892.1680
- **Device Class:** II

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

The identified predicate device(s) within this submission are as follows:

- **510(k) Number:** K193017
- **Manufacturer:** DRTECH Corporation
- **Common Name:** Digital Flat Panel X-ray Detector
- **Trade Name:** EVS 4343W, EVS 4343WG, EVS 4343WP, EVS 3643W, EVS 3643WG, EVS 3643WP
- **Classification Name:** Stationary X-ray System
- **Classification Panel:** Radiology
- **Product Code:** MQB
- **Regulation Number:** 21 CFR 892.1680
- **Device Class:** II

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

<Modification>

In comparison to existing devices, the new detectors incorporate a Flexible a-Si in the TFT material within the panel. The primary difference from the conventional glass a-Si panel is that the electronic circuits, such as silicon, are deposited on a plastic substrate instead of a glass substrate during the manufacturing of the TFT panel. Since only the material of the substrate on which the silicon is deposited changes, the overall image performance remains unaffected.

Another difference is the pixel pitch. While existing products feature only a pixel pitch of 140μm, the new models include an option with a pixel pitch of 100μm. The resolution of an X-ray detector has a significant impact on MTF (Modulation Transfer Function) and sensitivity.

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

The Digital X-ray detector, EXPD-N Series, is designed for use in digital imaging solutions for general radiographic diagnosis of human anatomy. This device is intended for use in all general diagnostic procedures, replacing film or screen-based radiographic systems for both adult and paediatric patients.
It is not intended for use in mammography.

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

The fundamental operational principle of the subject device is the same as that of the predicate device. The EXPD-N series detector is a square plate-shaped indirect conversion device that converts incoming X-rays into visible light. This visible light is subsequently captured by an optical sensor, which produces an electric charge representation of the spatial distribution of the incoming X-ray quanta.

Through thin film transistors, the charges are transformed into a modulated electrical signal. The signal is amplified, then changed from an analog to digital form (from voltage to signal) so that it can be printed out, sent for remote viewing, or saved as an electronic data file for later viewing.

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

Item	Subject Device(EXPD 4343S)	Predicate Device(EXPD 4343P)
510(k) No.	K243443	K193017
Manufacturer	DRTECH Corporation	DRTECH Corporation
Trade/ device Name	EXPD 4343N1, EXPD 4343N, EXPD 4343U1, EXPD 4343NU, EXPD 4343NP, EXPD 3643N1, EXPD 3643N, EXPD 3643U1, EXPD 3643NU, EXPD 3643NP	EVS 4343W, EVS 4343WG, EVS 4343WP EVS 3643W, EVS 3643WG, EVS 3643WP
Classification Name	Stationary X-ray System	Same
Classification Regulation	21 CFR 892.1680	Same
Product Code	MQB	Same
Device Class	Class II	Same

Item	Subject Device(EXPD 4343S)	Predicate Device(EXPD 4343P)
Intended Use	The Digital X-ray detector, EXPD-N Series, is designed for use in digital imaging solutions for general radiographic diagnosis of human anatomy. This device is intended for use in all general diagnostic procedures, replacing film or screen-based radiographic systems for both adult and paediatric patients. It is not intended for use in mammography.	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.
Anatomical Sites	General Radiography	Same
Dimensions (mm)	- EXPD 3643N/ EXPD 3643NP/ EXPD 3643NU / EXPD 3643N1/ EXPD 3643U1: 460(W) x 386(L) x 15.5(H)	- EVS 3643W/ EVS 3643WG/ EVS 3643WP: 460(W) x 386(L) x 15(H)mm
	- EXPD 4343N/ EXPD 4343NP/ EXPD 4343NU / EXPD 4343N1/ EXPD 4343U1: 460(W) x 460(L) x 15.5(H)mm	- EVS 4343W/ EVS 4343WG/ EVS 4343WP: 460(W) x 460(L) x 15(H)mm
Pixel Pitch	- EXPD 4343N / EXPD 4343NP / EXPD 4343NU / EXPD 3643N / EXPD 3643NP / EXPD 3643NU :140 ㎛	140µm
	- EXPD 4343N1 / EXPD 4343U1 / EXPD 3643N1 / EXPD 3643U1 : 100 ㎛	
Image Size (pixels)	- EXPD 4343N / EXPD 4343NP / EXPD 4343NU : 3,072 × 3,072	- EVS 3643W/ EVS 3643WG/ EVS 3643WP: 2,560 x 3,072 - EVS 4343W/ EVS 4343WG/ EVS 4343WP: 3,072 x 3,072
	- EXPD 3643N / EXPD 3643NP / EXPD 3643NU : 2,560 × 3,072	
	- EXPD 4343N1 / EXPD 4343U1 : 4,302 × 4,302	
	- EXPD 3643N1 / EXPD 3643U1 : 3,534 × 4,302	
Active Area (mm)	- EXPD 4343N / EXPD 4343NP / EXPD 4343NU : 430.2mm × 430.2mm	- EVS 3643W/ EVS 3643WG/ EVS 3643WP: 430mm x 358
	- EXPD 3643N / EXPD 3643NP / EXPD 3643NU : 353.4mm × 430.2mm	
	- EXPD 4343N1 / EXPD 4343U1 : 430.08mm × 430.08mm	- EVS 4343W/ EVS 4343WG/ EVS 4343WP: 430 x 430
	- EXPD 3643N1 / EXPD 3643U1 : 358.4mm × 430.08mm	
TFT Material	- EXPD 4343N1/ EXPD 4343N/ EXPD 3643 N1/ EXPD 3643N: a-Si	- EVS 3643W/ EVS 4343W/ EVS 3643WG/ EVS 4343WG: a-Si
	- EXDP 4343U1/ EXPD 4343NU/ EXPD 3643U1 / EXPD 3643 NU: Flexible a-Si	
	- EXPD 4343NP/ EXPD 3643NP: IGZO	- EVS 4343WP/ EVS 3643WP: IGZO
Cycle Time	≤ 8.5 sec.	Same
Power Supply	100~240V~, 50/60 Hz	Same
Dynamic Range	16 bits	Same
MTF	- EXPD 4343N/ EXPD 4343NP/ EXPD 4343NU /EXPD 3643N/ EXPD 3643NP/EXPD 3643NU : 35% *2.0lp/mm	- 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 4343WG: 50.1% at 2.0 lp/mm - EVS 3643WG: 47.8% at 2.0 lp/mm
	- EXPD 4343N1 / EXPD 4343U1 / EXPD 3643N1 / EXPD 3643U1 : 40% *2.0lp/mm	
DQE	- EXPD 4343N /EXPD 4343NP /EXPD 4343NU /EXPD 3643N /EXPD 3643NP /EXPD 3643NU : 60% *0.5lp/mm	- 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
	- EXPD 4343N1 /EXPD 4343U1 /	- EVS 4343WG: 25.1% at 1.0 lp/mm

Item	Subject Device(EXPD 4343S)	Predicate Device(EXPD 4343P)
	EXPD 3643N1 / EXPD 3643U1 : 60% *0.5lp/mm	- EVS 3643WG: 25.9% at 1.0 lp/mm
Resolution	- EXPD 4343N / EXPD 4343NP / EXPD 4343NU / EXPD 3643N / EXPD 3643NP / EXPD 3643NU : 3.5 lp/mm	3.5 lp/mm
	- EXPD 4343N1 / EXPD 4343U1 / EXPD 3643N1 / EXPD 3643U1 : 5 lp/mm	
Communication Method	Wire communication	Same
	Wireless communication : IEEE 802.11n/ac (2.4 GHz / 5 GHz)	Wireless communication : IEEE 802.11a/g/n (2.4 GHz / 5 GHz)
Software (Image Processing program)	EConsole 2(K240243)	EConsole 1(K152172)

The table above presented similarities(or identicality) between the subject device and predicate devices in:

- Intended Use
- Applied Anatomical Sites
- Technological Characteristics and Operating Principle
- Communication Method
- Size (Dimensions)
- Power Supply
- Dynamic Range

Following parts that shown differences between two devices,

- Image size
- Active area
- Pixel pitch and Resolution
- MTF and DQE
- TFT material
- Components

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

Non-clinical performance testing in major physical values, such as MTF and DQE, performed in comparison with the predicate device for evaluation. Additionally, clinical images acquired from various anatomical sites were reviewed by qualified expert clinicians to assess imaging performance. The results demonstrated that the device produces accurate X-ray images suitable for diagnostic purposes.

Besides performance testing in comparison with predicate device, Electrical Safety testing and Electromagnetic compatibility testing was performed in accordance with IEC 60601-1 and IEC 60601-1-2, and results met the requirements.

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

The clinical studies are not required as there are no significant changes that requires assess of the performance made in the subject device, such as new indication, and non-clinical testing demonstrated equivalency to the predicate device sufficiently.

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

The subject device, EXPD 4343N1, EXPD 4343N, EXPD 4343U1, EXPD 4343NU, EXPD 4343NP, EXPD 3643N1, EXPD 3643N, EXPD 3643U1, EXPD 3643NU, and EXPD 3643NP is substantially equivalent to the currently marketed predicate device in terms of technical characteristics, design features, operating principles, basis of functional and performance characteristics. Furthermore, the modification does not change to its intended use and indications for use.