February 13, 2024

DRTECH Corporation
℅ Lee Juhee
Assistant Manager
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: K232082
Trade/Device Name: EXPD 4343s
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary X-Ray System
Regulatory Class: Class II
Product Code: MQB
Dated: January 12, 2024
Received: January 16, 2024

Dear Lee Juhee:

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.

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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological Imaging
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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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K232082

Device Name

EXPD 4343S

Indications for Use *(Describe)*

The EXPD 4343S Digital X-ray detector is indicated for use in generating radiographic images of human anatomy. This device is intended to replace film or screen based radiographic systems in all general purpose diagnostic procedures on general populations.
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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DRTECH

K232082

510(k) Summary

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)]

July 12, 2023

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

- **Trade/ Device Name:** EXPD 4343S
- **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:** K193031
- **Manufacturer:** DRTECH Corporation
- **Common Name:** Digital Flat Panel X-ray Detector
- **Trade Name:** EXPD 4343P, EXPD 3643P
- **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>

Addition of EXPD 4343S: The subject and predicate devices differ in active matrix arrays and performance (MTF & DQE). The subject device features two matrix arrays, while the predicate device incorporates only one.
Fundamentally, the active matrix array's main role is to convert incoming electrical information from the photodiode layer into visual images. The density and thickness of the human body and tissues influence the resulting images, consequently different parameters must be used for different body areas or patient conditions.

Within the subject device, the two matrix arrays are strategically positioned in an overlapping configuration within the housing. This arrangement facilitates the generation of multiple images with a single exposure. "Array #1*" works similarly to the predicate device by detecting incident X-ray photons and converting them into electrical signals. Simultaneously, "Array #2" captures unabsorbed X-rays from "Array #1**" after passing through it.

As a consequence of this configuration, the subject device has the capacity to produce three distinct images. The Standard image, similar to the predicate device, is generated by "Array #1.", and second image is generated by “Array #2". The both images are transmitted to Console software.
Finally, three images are formed: a Standard image produced by "Array #1," a second image (a soft tissue image) obtained by processing the Standard image using Console software, and a third image (a bone image) generated by processing the image obtained from “Array #2”.

Aside from the number of matrix arrays, the rest of the parts are nearly identical to the predicate device; the operational mechanism is the same, the major components and materials that influence device performance and safety remain unchanged.

** Array #1: X-ray imaging sensor array located on the X-ray entrance side.*
*** Array #2: X-ray imaging sensor array located on the opposite side of the X-ray entry.*

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

The EXPD 4343S Digital X-ray detector is indicated for use in generating radiographic images of human anatomy. This device is intended to replace film or screen based radiographic systems in all general purpose diagnostic procedures on general populations.
This device is not intended for mammography applications.

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 4343S 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.	-	K193031
Manufacturer	DRTECH Corporation	DRTECH Corporation
Trade/ device Name	EXPD 4343S	EXPD 4343P, EXPD 3643P
Classification Name	Stationary X-ray System	Same
Classification Regulation	21 CFR 892.1680	Same
Product Code	MQB	Same
Device Class	Class II	Same
Intended Use	The EXPD 4343S Digital X-ray detector is indicated for use in generating radiographic images of human anatomy. This device is intended to replace film or screen based radiographic systems in all general Purpose diagnostic procedures on general populations. This device is not intended for mammography applications.	The EXPD 4343P / EXPD 3643P 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)	460(W) x 460(L) x 15.5(H)	460(W) x 483(L) x 15.5(H)
Pixel Pitch	140μm	Same
Image Size (pixels)	3,072 x 3,072	Same
Active Area (mm)	430 x 430	Same
Scintillator/ TFT Material	CsI/ IGZO	Same
Scintillator Thickness	Total: 1,000μm (Two scintillators are included, each with a thickness of 500μm.)	350μm
Resolution	3,072×3,072 pixel	Same
Cycle Time	≤ 8.5 sec.	Same
Power Supply	100~240V~, 50/60 Hz	Same
Dynamic Range	16 bits	Same
MTF	45 % at 2.0 lp/mm	52 % at 2.0 lp/mm
DQE	55 % at 0.5 lp/mm	Same
Communication Interface	Wired	Same
Software (Image Processing program)	EConsole 1(K231225)	EConsole 1(K152172)

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

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

The differences between the subject device and predicate device in:

- Scintillator Thickness
- MTF value
- Software(Image processing program)
- Number of matrix arrays

The EConsol 1 software is utilized for both predicate and subject devices. But since the subject device can produce three different images—a standard image, a soft tissue image, and a bone image—the EConsol 1 software with the soft tissue and bone image display function was approved under K231225. The software's basic working principles with the detectors remain unchanged.

The subject device's scintillator thickness is slightly thicker than that of the predicate device, causing it to absorb more X-rays and affecting the MTF and DQE values; however, an overall assessment of the subject device's essential performance revealed that it is basically on the equivalent level with the predicate device.

In addition to the performance testing, the clinical image evaluation was performed to assess the device's clinical performance and average score of evaluation results by two experienced physicians demonstrated that the device is prove to be effective in clinical practice.

Although there are some differences, the operational mechanism remains consistent, and the primary components and materials that influence device performance and safety remain unchanged. The subject device employs the same components as the predicate device, the it has undergone electrical safety testing in accordance with IEC 60601-1, as well as electromagnetic compatibility testing in accordance with IEC 60601-1-2.
Therefore, we claim that the EXPD 4343S is safe and effective for its intended use as the predicate device.

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.

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 image evaluation was carried out by two experienced physicians.
Chest PA imaging sets used for evaluation in the report were acquired in the same condition, and visual system was adapted with each physician's overall assessment. The result showed that images acquired by the subject device were generally in diagnostic quality, and evaluators stated that the device proved to be effective use in clinical practice.

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

The modified EXPD 4343S detector 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.
Additionally, comprehensive non-clinical performance evaluations were conducted in accordance with FDA-recognized consensus standards, demonstrating substantial equivalence. The results of these evaluations met the required criteria.

Based on the provided comparison table and summarized supporting data, it is concluded that the modification made to the EXPD 4343S detector does not raise any safety or performance concerns. Consequently, the subject device is substantially equivalent to the predicate device in terms of safety and effectiveness.