DRTECH Corporation
An Yeong-Suk
Assistant Manager
Suite No.1, 2 Floor / Suite No. 2, 3 Floor
29, Dunchon-daero 541 beon-gil, Jungwon-gu
Seongnam-si, Gyeonggi-do 13216
Korea, South

September 23, 2024

Re: K240243
Trade/Device Name: EConsole2
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: August 14, 2024
Received: August 14, 2024

Dear An Yeong-Suk:

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,

Jessica Lamb

Jessica Lamb, PhD
Assistant Director, Imaging Software Team
DHT8B: Division of Radiologic 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.

510(k) Number *(if known)*
K240243

Device Name
EConsole2

Indications for Use *(Describe)*
EConsole2 is indicated for use in general radiographic images of human anatomy. It is intended to replace radiographic film/screen systems in all general-purpose diagnostic procedures (excluding fluoroscopic, angiographic, and mammographic applications). It is intended for both adult and pediatric populations.

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, Seongnam-si,
Gyeonggi-do, 13216, Republic of Korea

DRTECH

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)]

September/20/2024

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

- Name of Sponsor: DRTECH Corporation
- Address: Suite No.1, 2 Floor / Suite No. 2, 3 Floor, 29, Dunchon-daero 541 beon-gil, Jungwon-gu, Seongnam-si, Gyeonggi-do, 13216, Republic of Korea
- Contact Name: Yeongsuk An
- Telephone No.: + 82-31-779-7787
- Fax No.: + 82-31-779-7790
- Email Address : drtechra@drtech.com
- Registration Number: 3005172103
- Name of Manufacturer: Same as Sponsor

3. Identification of the Subject Device [21 CFR 807.92(a) (2)]

- Model Name: EConsole2
- Common Name: Radiological Image Processing System
- Classification Name: Medical image management and processing system
- Classification Panel: Radiology
- Classification Regulation: 21 CFR 892.2050
- Primary Product Code: LLZ
- Device Class: II

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

4.1 Predicate device

- 510(k) Number: K231225
- Applicant: DRTECH Corporation
- Trade Name: EConsole1
- Classification Name: Medical image management and processing system
- Classification Panel: Radiology
- Classification Regulation: 21 CFR 892.2050
- Product Code: LLZ
- Device Class: II

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

EConsole2 is digital radiography operating console software. EConsole2 provides an integrated solution for X-ray projection. It integrates with the digital detector. Furthermore, EConsole2 acquires and processes images. In addition, it complies with DICOM standards and is able to transmit and receive data with the PACS system, and print images through the DICOM printer.

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

EConsole2 is indicated for use in general radiographic images of human anatomy. It is intended to replace radiographic film/screen systems in all general-purpose diagnostic procedures (excluding fluoroscopic, angiographic, and mammographic applications). It is intended for both adult and pediatric populations.

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

The EConsole2 is a x-ray image software device. It can utilize and transfer the digitalizing x-ray images for radiography diagnostic. It can work with Modality worklist, PACS and DICOM Printer to maintain the patient information and the images from flat panel detector.

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

Parameter	Proposed Device	Predicate Device	Equivalence Analysis
510(k) Number	Unknown	K231225	N/A
Model Name	EConsole2	EConsole1	N/A
Manufacturer	DRTECH Corporation	DRTECH Corporation	N/A
Common Name	Radiological Image Processing System	Radiological Image Processing System	N/A
Classification Name	Medical image management and processing system	Medical image management and processing system	N/A
Classification Panel	Radiology	Radiology	Equivalence
Classification Regulation	21 CFR 892.2050	21 CFR 892.2050	Equivalence
Product Code	LLZ	LLZ	Equivalence
Device Class	Class II	Class II	Equivalence

Intended Use	EConsole2 is indicated for use in general radiographic images of human anatomy. It is intended to replace radiographic film/screen systems in all general-purpose diagnostic procedures (excluding fluoroscopic, angiographic, and mammographic applications). It is intended for both adult and pediatric populations.	EConsole1 is indicated for use in general radiographic images of human anatomy. It is intended to replace radiographic film/screen systems in all general-purpose diagnostic procedures (excluding fluoroscopic, angiographic, and mammographic applications).	Similar
Software Function	Image acquisition and study Image search Image storage Image annotation Image measurement Image stitch Image processing Generator Control	Image acquisition and study Image search Image storage Image annotation Image measurement Image stitch Image processing Generator Control	Similar
DICOM Compliance	Yes	Yes	Equivalence

When compared to the predicate devices (K231225), the device proposed in this submission, EConsole2, has the equal to the followings as the predicate device and reference device:

• Intended Use

• Software function

• Technological characteristics

In case of Technological characteristics, all items are the same, but some items have detailed optional functions. Please refer to the below table.

Software Function		Technological characteristics		Equivalence Analysis
		Proposed Device(Non)	Predicate Device(K231225)	
Generator Control		This function controls the generator to set X-ray irradiation conditions(such as kVp, mA, mAs, etc.) can be adjusted. And this function transmit the set data to the generator. Then It is displayed the set X-ray irradiation conditions, and displays the image acquired after X-ray irradiation. But this control function of EConsole2 does not exerts control over generator power that produces ionizing radiation. However, Its does not have control over exposure, electrical changes, or the calibration of the X-ray system.	This function controls the generator to set X-ray irradiation conditions(such as kVp, mA, mAs, etc.) can be adjusted. And this function transmit the set data to the generator. Then It is displayed the set X-ray irradiation conditions, and displays the image acquired after X-ray irradiation. But this control function of EConsole2 does not exerts control over generator power that produces ionizing radiation. However, Its does not have control over exposure, electrical changes, or the calibration of the X-ray system.	Equivalence
DEXi Function		1. When generator which supports DEXi and when examining DEXi, mark the irradiation condition(High kV, High mA, High mAs, Low kV, Low mA, Low mAs) and provide button to control the irradiation condition. 2. When changing the irradiation condition, connect with generator and control the irradiation condition.	1. When generator which supports DEXi and when examining DEXi, mark the irradiation condition(High kV, High mA, High mAs, Low kV, Low mA, Low mAs) and provide button to control the irradiation condition. 2. When changing the irradiation condition, connect with generator and control the irradiation condition.	Equivalence
Image Processing(Optional)	Truveiw ART	Increase the sharpness of the obtained x-ray images.	Increase the sharpness of the obtained x-ray images.	Equivalence
	ECE Function	ECE function can be applied before the main image processing. This function normalizes the image brightness and contrast regardless of the exposed x-ray dose. ECE function works as a simple linear transformation to each pixel value. To find the slope and the offset of the linear function, ECE function first finds two or more reference points in the radiograph. The reference points are selected depending on the body part and position of the patient. By using these reference points, we can determine the	N/A	This is new function of EConsole2.

		slope and the offset of the linear function. Finally, by using the inverse of the linear function, the brightness and the contrast of the radiograph will be normalized even with different x-ray exposure condition. And now some desired function, such as gamma correction or LUT, can be applied. With ECE function, the main image processing engine can expect an image with similar brightness and contrast regardless of the x-ray exposure condition. Therefore, the resulting radiograph will have more uniform image quality. The user cannot change the parameters of this function or turn it off. Only the engineers can change. And this function is used for all of the body parts including chest, abdomen, pelvis, skull, extremities and etc.		

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

The EConsole2 complies with the following international and FDA-recognized consensus standards list in Table 2.

Table 2. International and FDA-recognized consensus standards

Recognition No.	Standard No.	Title of Standard	Remark
13-79	IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION	Medical device software - Software life cycle processes	
13-129	ISO IEC IEEE 29119-1 First edition 2013-09-01	Software and systems engineering - Software testing - Part 1: Concepts and definitions	
12-349	NEMA PS 3.1 - 3.20 2022d	Digital Imaging and Communications in Medicine (DICOM) Set	
5-135	ISO 20417 First edition 2021-04 Corrected version 2021-12	Medical devices - Information to be supplied by the manufacturer	
5-129	IEC 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION	Medical devices - Part 1: Application of usability engineering to med	
5-125	ISO 14971 Third Edition 2019-12	Medical devices - Application of risk management to medical device	
13-96	UL ANSI 2900-1 First Edition 2017	Standard for Safety, Standard for Software Cybersecurity Network-Connectable Products, Part 1: General Requirements	

And EConsole2 comply with the FDA guidance documents listed in Table 3.

Table 3. FDA Guidance Documents

Title of Guidance Document	**Issue Date**
Guidance for Industry and Food and Drug Administration Staff: The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]	July 28, 2014
Content of Premarket Submissions for Device Software Functions, Guidance for Industry and Food and Drug Administration Staff	June 14, 2023
Off-The-Shelf Software Use in Medical Devices	August 11, 2023

Title of Guidance Document	Issue Date
Cybersecurity in Medical Devices Quality System Considerations and Content of Premarket Submissions	September 26, 2023
Pediatric Information for X-ray Imaging Device Premarket Notifications, Guidance for Industry and Food and Drug Administration Staff	November 28, 2017

The risk analysis was completed and risk controls were implemented to mitigate identified hazards. The test results support that all the specifications have met the acceptance criteria. Verification and validation testing were found acceptable to support the claim of substantial equivalence.

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

Not Applicable

Clinical studies are unnecessary to validate the safety and effectiveness of the Radiological Image Processing System, EConsole2, the subject of this 510(k) notification.

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

The EConsole2 is substantially equivalent to the currently marketed predicate device (K231225, EConsole1) in terms of technical characteristics, general function, application and indications for use, safety, and effectiveness. Substantial equivalence for Radiological Image Processing System (EConsole2) was demonstrated through the non-clinical performance in compliance with the requirements specified in the international and FDA recognized consensus standards, IEC 62304, IEC 62366-1, and UL ANSI 2900-1.

The comparison of technological characteristics, non-clinical performance data and safety testing demonstrate that the EConsole 2 is substantially equivalent to the predicate devices.