October 18, 2023

DRTECH Corporation
% Kim Hanbyul
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
SOUTH KOREA

Re: K231225
Trade/Device Name: EConsole1
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: September 19, 2023
Received: September 19, 2023

Dear Kim Hanbyul:

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 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231225

Device Name
EConsole1

Indications for Use *(Describe)*
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).

The main features of this software are controlling and interfacing the detector, controlling the x-ray generator acquisition settings, storing acquired images, data management and image processing.

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.

510(k) Summary

K231225

[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)]

October 17, 2023

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: Hanbyul Kim
- Telephone No.: + 82-31-779-7720
- Fax No.: + 82-31-779-7790
- Email Address : hbkim95@drtech.com
- Registration Number: 3005172103
- Name of Manufacturer: Same as Sponsor

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

- Trade Name: EConsole1
- Common Name: Radiological Image Processing System
- Classification Name: Medical image management and processing system
- Classification Panel: Radiology
- Classification Regulation: 21 CFR 892.2050
- Product Code: LLZ
- Device Class: II

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

4.1 Primary predicate device

- 510(k) Number: K110033
- Applicant: IMFOU CO., LTD
- Trade Name: FEEL-DRCS
- Classification Name: Medical image management and processing system
- Classification Panel: Radiology
- Classification Regulation: 21 CFR 892.2050
- Product Code: LLZ
- Device Class: II

4.2 Reference predicate device

- 510(k) Number: K152172
- 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)]

Radiological Image Processing Software, EConsole1 is complete digital image processing console software specialized for the digital X-ray detector series developed by DRTECH Corporation.

EConsole1 not only processes the acquired images but also complies with DICOM standards which allow the user 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)]

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).

The main features of this software are controlling and interfacing the detector, controlling the x-ray generator acquisition settings, storing acquired images, data management and image processing.

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

EConsole1 is medical software. It digitalizes the signal sent from the detector and displays the x-ray image. Also, it can enter patient information, shot information, and other necessary references for convenience.

Compared with the predicate device, the technological characteristics of the proposed device, Econsole1, are substantially equivalent to those of the predicate device. The proposed device is functionally similar to the predicate device.

Additionally, our device does not exert control over generator power that produces ionizing radiation. The control function of the X-ray generator is dependent on the specific X-ray Generator company, as EConsole1 can only interface and be controlled using the protocol provided by that particular company. Moreover, EConsole1 can only select or modify values of X-ray exposure parameters (such as kVp, mA, second, or kVp; mAs) according to the defined values set by each X-ray company. However, EConsole1 does not have control over exposure, electrical changes, or the calibration of the X-ray system. Therefore, it is necessary for the radiological technician to check the X-ray exposure conditions on the console of the X-ray Generator before conducting any X-ray procedures. If the X-ray generator does not allow interface with external software, such as EConsole1, the software will not be able to interface with the X-ray Generator.

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

Parameter	Subject Device	Predicate Device	Reference Device	Comparison Analysis
510(k) Number	Unknown	K110033	K152172	N/A
Model Name	EConsole1	FEEL-DRCS	EConsole1	N/A
Manufacturer	DRTECH Corporation	IMFOU CO., LTD	DRTECH Corporation	N/A
Common Name	Radiological Image Processing System	Radiological Image Processing System	Radiological Image Processing System	Identical
Classification Name	Medical image management and processing system	Medical image management and processing system	Medical image management and processing system	Identical
Classification Panel	Radiology	Radiology	Radiology	Identical
Classification Regulation	21 CFR 892.2050	21 CFR 892.2050	21 CFR 892.2050	Identical
Product Code	LLZ	LLZ	LLZ	Identical
Device Class	Class II	Class II	Class II	Identical
Intended Use	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). The main features of this software are controlling and interfacing the detector, controlling the x-ray generator acquisition settings, storing acquired images, data management and image processing	feel-DRCS software using a digital X-ray detector is the digital X-ray image processing system designed to acquire images and process acquired images efficiently. The main features of this software are controlling and interfacing the detector, acquiring images after X-ray, storing acquired images, managing data, optimizing window level and width of acquired images, rotating images, zooming images, measuring images and so on. feel-DRCS is compatible with DICOM 3.0 standard. It can transfer images processed in PACS and print images with a film printer	The Econsole1 software is indicated for use in general radiographic images of human anatomy (excluding fluoroscopic, angiographic, and mammographic applications).	Identical

		compatible with DICOM 3.0 by using DICOM and network systems. feel-DRCS is not approved for the acquisition of mammographic image data and is meant to be used by qualified medical personnel only. All users must be qualified to create and diagnose radiological image data. feel-DRCS is not approved for the acquisition of mammographic image data.		
Acquisition devices	Digital X-ray Detector	Digital X-ray Detector	Digital X-ray Detector	Identical
Software Function	Image viewing Image search Image storage Image annotation Image measurement Image processing Image stitch Generator Control	Image viewing Image search Image storage Image annotation Image measurement Image processing Image stitch Generator Control	Image viewing Image search Image storage Image annotation Image measurement Image processing Image stitch	Identical
DICOM Compliance	Yes	Yes	Yes	Identical

When compared to the predicate devices (K110033), the device presented in this submission, EConsole1, has the same of the followings as the predicate device:

- Intended Use
- Performance properties
- Technological characteristics
- Software function

There are no significant differences between the EConsole1 and the predicate device that would have a negative impact on the product's use. Therefore, the subject device is considered substantially equivalent to the predicate device.

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

The EConsole1 complies with the following 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	
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	

Software Verification and Validation

As part of this submission, the Software Documentation for a Medical Device with Moderate Level of Concern, as outlined in the FDA's Guidance Document *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" dated May 11, 2005*, is also provided.

The data indicates that medical devices containing software adhere to special controls consistently. During the product development of EConsole1, various non-clinical tests such as code, module, integration, and dynamic tests were conducted. A risk analysis was carried out, and risk controls were put in place to mitigate identified hazards. The test results suggest that all software specifications meet the acceptance criteria. Furthermore, the verification and validation testing were deemed acceptable, thereby supporting the claim of substantial equivalence.

Cybersecurity

EConsole1 conforms to Section 6 of the *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices Guidance for Industry and Food and Drug Administration Staff (October 2, 2014),* to maintain confidentiality, integrity, and availability. Additionally, EConsole1 is linked through DICOM standards to medical devices and a PACS system, which stores data generated by the medical devices. It retrieves image data via network communication based on DICOM standards. Therefore EConsole1 assures an adequate degree of protection for cybersecurity.

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

Clinical studies are unnecessary to validate the safety and effectiveness of the software in EConsole1, the subject of this 510(k) notification.

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

EConsole1 is substantially equivalent to the predicate device. It has the same intended use, performance properties and technological characteristics as its predicate device.

EConsole1 passed all Verification and Validation testing, which means that the features, functions and technology were all demonstrated to perform well. Performance data also demonstrates that EConsole1 is both safe and effective in its intended performance.

Therefore, EConsole1 does not introduce any new potential safety risks and is substantially equivalent to the predicate device.