



Food and Drug Administration
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December 14, 2015

DRTECH Corporation
% Mr. Choul-Woo Shin
Vice President
Suite No. 2, 3 Floor, 29, Dunchon-daero541beon-gil,
Jungwon-gu, Seongnam-si, Gyeonggi-do 462-807
REPUBLIC OF KOREA

Re: K152172
Trade/Device Name: EConsole1
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: October 21, 2015
Received: November 4, 2015

Dear Mr. 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink that reads "Robert Ochs". The signature is written in a cursive style with a slight shadow effect behind the text.

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K152172

Device Name

Econsole1

Indications for Use (Describe)

The Econsole1 software is indicated for use in general radiographic images of human anatomy (excluding fluoroscopic, angiographic, and mammographic 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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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)]

07/31/2015

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

Name of Sponsor: DRTECH Corporation.
Address: Suit No. 2, 3 Floor, 29, Dunchon-daero541 beon-gil,
Jungwon-gu, Seongnam-si, Gyeonggi-do 462-807
Republic of Korea
Contact Name: Choul-Woo Shin
Telephone #: +82-31-784-8856
Fax #: +82-31-784-8899
Email: cwshin@drtech.co.kr
Registration Number: 3005172103
Name of Manufacturer: Same as Sponsor

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

Model Name: Econsole1
Common Name: Radiological Image Processing System
Classification Name: Picture archiving and communications system
Classification Panel: Radiology
Classification Regulation: 21 CFR 892.2050
Product Code: LLZ
Device Class: 2

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

510(k) Number: K110033
Product Code: LLZ
Applicant: IMFOU CO., LTD
Model Name: FEEL-DRCS
Decision Date: 09/15/2011
Type: Traditional

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

Econsole1 is digital radiography operating console software. Econsole1 provides an integrated solution for X-ray projection. It integrates with the digital detector. Furthermore, Econsole1 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. Intended Use [21 CFR 807.92(a) (5)]

The Econsole1 software is indicated for use in general radiographic images of human anatomy (excluding fluoroscopic, angiographic, and mammographic applications).

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.

8. Substantial Equivalence [21 CFR 807.92(b) (1) and 807.92]

Parameter	Subject Device	Predicate Device
510(k) Number	Unknown	K110033
Model Name	Econsole1	FEEL-DRCS
Manufacturer	DRTECH Corporation	IMFOU CO., LTD
Common Name	Radiological Image Processing System	
Classification Name	Picture archiving and communications system	
Classification Panel	Radiology	
Classification Regulation	21 CFR 892.2050	
Product Code	LLZ	
Device Class	Class II	
Intended Use	The Econsole1 software is indicated for use in general radiographic images of human anatomy (excluding fluoroscopic, angiographic, and mammographic applications).	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.

		<p>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.</p> <p>feel-DRCS is compatible with DICOM 3.0 standard. It can transfer images processed in PACS and print images with a film printer compatible with DICOM 3.0 by using DICOM and network systems.</p> <p>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.</p> <p>feel-DRCS is not approved for the acquisition of mammographic image data.</p>
Acquisition devices	Digital X-ray Detector	Digital X-ray Detector
Software Function	<p>Image viewing Image search Image storage Image annotation Image measurement Image processing Image stitch</p>	<p>Image viewing Image search Image storage Image annotation Image measurement Image processing Image stitch Generator Control</p>
DICOM 3.0 Compatibility	Yes	Yes

9. Summary of Non-Clinical Data

Econsole1 complies with the FDA guidance document entitled 'Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices,' May 11, 2005

10. Summary of Clinical Data

This section is not applicable

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

When compared to the predicate devices (K110033), the Econsole1 presented in this submission has the same of the followings:

- Intended Use
- Technological characteristics
- Performance properties

The two devices share the difference performance as the following:

- Generator Control

The predicate device has a generator control feature, but Econsole1 does not include such feature. However, such feature does not make a big difference in fulfilling the intended use, which is acquiring images after X-ray and processing the images. Therefore, Econsole1 is substantially equivalent to the predicate device.