DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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February 23, 2017

DRTECH Corporation
% Mr. Choul-Woo Shin
Vice President
Suite No. 2, 3 Floor, 29, Dunchon-daero541 beon-gil, Jungwon-gu
Seongnam-si, Gyeonggi-do 13230
REPUBLIC OF KOREA

Re: K162670
Trade/Device Name: RSM 1824C with RConsole1
Regulation Number: 21 CFR 892.1715 and 21 CFR 892.2050
Regulation Name: Full-field digital mammography system and Picture archiving and communications system
Regulatory Class: II
Product Code: MUE, LLZ
Dated: January 20, 2017
Received: January 23, 2017

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,

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162670

Device Name
RSM 1824C with RConsole1

Indications for Use *(Describe)*
The RSM 1824C is a detector indicated for use in screening and diagnostic mammography.

The RConsole1 is an integrated software solution indicated for use with the RSM Series detectors.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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)]

10/25/2016

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 13230 Republic of Korea
- Contact Name: Choul-Woo Shin
- Telephone No.: + 82-31-779-7783
- Fax No.: + 82-31-779-7790
- Email Address : 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)]

	Detector (RSM 1824C)	Software (Rconsole1)
• Trade Name	RSM 1824C with RConsloe1	
• Common Name	Digital Flat Panel X-ray Detector	Radiological Image Processing System
• Classification Name	Full Field Digital, System, X-ray, Mammographic	Picture archiving and communications system
• Classification Panel	Radiology	
• Classification Regulation	21 CFR 892.1715	21 CFR 892.2050
• Product Code	MUE	LLZ
• Device Class	II	

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

	For Detector	For Software
• 510(k) Number	P010025	K152172
• Applicant	HOLOGIC, INC.	DRTECH CORPORATION
• Trade Name	Lorad Digital Breast Imager (LDBI)	Econsole1
• Classification Name	Full Field Digital, System, X-ray, Mammographic	Picture archiving and communications system
• Classification Panel	Radiology	
• Classification Regulation	21 CFR 892.1715	21 CFR 892.2050
• Product Code	MUE	LLZ
• Device Class	II	
• Remark	The predicate device that has been reclassified from Class III to II	

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

The RSM 1824C detector panel is an indirect conversion device in the form of a square plate in which the input x-ray photons are absorbed in an x-ray sensitive scintillator layer. The energy of the incoming photons generates light distribution in the scintillator layer. Light is converted to a modulated electrical signal through PIN diode within the pixel of the thin film transistor. The amplified signal is converted to a voltage signal and is then converted from an analog to digital signal which can be transmitted to a viewed image print out, transmitted to remote viewing or stored as an electronic data file for later viewing.

The RSM 1824C consists of main components such as SSU (System Synchronization Unit: RSM-SSU01, RSM-SSU02 (Code# B12160000)), LAN Cable (Code# C20050502) and POE Cable (Code# C16050700), Power Cord (Code# E00050023), Ethernet Adaptor and software CD.
The System Synchronization Units, RSM-SSU01 and RSM-SSU02, only differ in their sizes. Only one System Synchronization Unit will be provided to the customer based on their choice. Also, only one System Synchronization Unit can be connected to the one detector.

The RConsole1 is digital radiography operating console software specialized for the RSM series, a digital X-ray detector developed by DRECH Inc.
RConsloe1 provides an integrated solution for X-ray projection. It integrates with the X-ray generator and the digital detector and 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 RSM 1824C is a detector indicated for use in screening and diagnostic mammography.

The RConsole1 is an integrated software solution indicated for use with the RSM Series detectors.

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

The RSM 1824C detector panel is an indirect conversion device in the form of a square plate in which the input x-ray photons are absorbed in an x-ray sensitive scintillator layer. The energy of the incoming photons generates light distribution in the scintillator layer. Light is converted to a modulated electrical signal through PIN diode within the pixel of the thin film transistor. The amplified signal is converted to a voltage signal, and then it is converted from an analog to digital signal which can be transmitted to a print-out image viewer, transmitted to remote viewing, or stored as an electronic data file for later viewing.
Based on a technical feature comparison, the subject device was found to be similar to the predicate device in regards of detector technology (CsI).

Rconsole1 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, Rconsole1, 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)]

Parameter	Subject Device	Predicate Device		Remark
		For Detector	For Software	
510(K) Number	Unknown	P010025	K152172	-
Manufacturer	DRTECH Corporation	HOLOGIC, INC.	DRTECH Corporation	-
Model Name	RSM 1824C with Rconsole1	Lorad Digital Breast Imager (LDBI)	Econsole1	-
Classification Name	Full Field Digital, System, X-ray, Mammographic	Full Field Digital, System, X-ray, Mammographic	Picture archiving and communications system	same
Classification Panel	Radiology			same
Classification Regulation	21 CFR 892.1715, 21 CFR 892.2050	21 CFR 892.1715	21 CFR 892.2050	same
Product Code	MUE, LLZ	MUE	LLZ	same
Device Class	Class II			same
Intended Use	The RSM 1824C is a detector indicated for use in screening and diagnostic mammography. The RConsole1 is an integrated software solution indicated for use with the RSM Series detectors.	The Lorad Digital Breast Imager generates digital mammographic images that can be used for screening and diagnosis of breast cancer. The Lorad Digital Breast Imager is intended to be used in the same clinical applications as traditional screen-film mammographic systems.	The Econsole1 software is indicated for use in general radiographic images of human anatomy (excluding fluoroscopic, angiographic, and mammographic applications).	same
Pixel Pitch	76 μm	40 μm	N/A	different
Image Size	233.4 x 175.1mm	186 x 248 mm	N/A	similar
Materials Scintillator	CsI	CsI:Tl	N/A	same
DQE	50% at 1 lp/mm 43% at 2 lp/mm	45% at 1 lp/mm 35% at 2 lp/mm 30% at 3 lp/mm 24% at 4 lp/mm	N/A	similar
MTF	70% at 2 lp/mm 20% at 5 lp/mm	70% at 2 lp/mm 30% at 5 lp/mm 6% at 10 lp/mm	N/A	similar

Resolution	3,072 x 2,304	4,800 x 6,400	N/A	different
Detector Type	TFT a-Si	CCD CsI:Tl	N/A	different
Acquisition devices	Digital X-ray Detector	Digital X-ray Detector	Digital X-ray Detector	same
Software Function	Image viewing Image search Image storage Image annotation Image measurement Image processing Image stitch	Not Known	Image viewing Image search Image storage Image annotation Image measurement Image processing Image stitch	same
DICOM 3.0 Compatibility	Yes	Yes	Yes	same

The predicate devices (P010025, K152172) and the subject device, RSM 1824C/Rconsole1 are equivalent in terms of the following matters:

- Intended Use
- Technological characteristics
- Operating principle
- Design features
- Image Size
- Performance (DQE, MTF)
- Software function

A few differences are as follows

- Performance (Pixel Pitch, Resolution)
- Detector Type

There is no significant difference between the RSM 1824C/Rconsole1 and the predicate device that would adversely affect the use of the product. The subject device is substantially equivalent to the predicate device in design, function, materials, operational principles, intended use software function.

Even though the predicate device and the subject device differ in the pixel pitch, resolution and types of the detector, the differences are not critical in terms of the diagnostic purposes because the clinical image evaluation demonstrate that the subject devices are substantially equivalent to the predicate device.

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

The non-clinical performance tests were performed to evaluate the Sensitometric Response(=Pixel Response), Spatial resolution - Modulation Transfer Function (MTF), Noise analysis - Noise Power Spectrum (NPS), Signal-to-noise ratio transfer - Detective Quantum Efficiency (DQE), Dynamic range, Phantom testing, Image erasure and fading, Repeated exposure testing (Ghosting), Patient radiation dose and Automatic exposure control performance.

The RSM 1824C complies with the following international and FDA-recognized consensus standards:

AAMI ANSI ES60601-1: Medical Electrical Equipment -- Part 1: General Requirements for Basic Safety And Essential Performance (IEC 60601- 1:2005, Mod)

IEC 60601-1-2:	Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance – Collateral Standard: Electromagnetic Compatibility - Requirements And Tests (Edition 3)
ISO 14971:	Medical Devices - Application of Risk Management to Medical Devices. (General I (QS/RM))
IEC 62220-1:	Medical electrical equipment - Characteristics of digital X-ray imaging devices - Part 1: Determination of the detective quantum efficiency
IEC 61267:	Medical Diagnostic X-ray Equipment – Radiation Conditions for Use in the Determination of Characteristics
NEMA PS 3.1 - 3.20:	Digital Imaging and Communications in Medicine (DICOM) Set

Rconsole1 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 [21 CFR 807.92(b)(2)]

The single-blinded concurrence study conducted in compliance with CDRH's Guidance (Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Full Field Digital Mammography System) confirmed that the new x-ray detectors (RSM 1824C) provide images of equivalent diagnostic capability to the predicate device. The results of the study demonstrate substantial equivalence.

This section is not applicable to Rconsole1.

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

The RSM 1824C/Rconsole1 is substantially equivalent to the currently marketed predicate device (Lorad Digital Breast Imager (P010025) and Econsole1 (K152172)) in terms of design, fundamental scientific technology, indications for use, safety, and effectiveness.

Substantial equivalence for detector (RSM 1824C) was demonstrated through the non-clinical performance in compliance with the requirements specified in the international and FDA recognized consensus standards, AAMI ANSI ES60601-1, IEC 60601-1-2, ISO 14971, IEC 62220-1 and NEMA PS 3.1 - 3.20. Also, substantial equivalence was demonstrated through a clinical test, which was conducted in compliance with the requirements specified in the "CDRH's Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Full Field Digital Mammography System".
The results of these tests demonstrate that the RSM 1824C meets the acceptance criteria, and the device is adequate for its intended use. The comparison of technological characteristics, non-clinical performance data, safety testing, and clinical image concurrence data demonstrate that the RSM 1824C is substantially equivalent to the predicate devices (Lorad Digital Breast Imager).

Additionally, when compared to the predicate the device (K152172), The Rconsole1 presented in this submission has the same of the intended use, technological characteristics, performance properties and software function. Therefore, Rconsole1 is substantially equivalent to the predicate device (Econsole1).