



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

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

April 27, 2017

Re: K170930
Trade/Device Name: RSM 2430C
Regulation Number: 21 CFR 892.1715
Regulation Name: Full-Field Digital Mammography System
Regulatory Class: Class II
Product Code: MUE
Dated: March 24, 2017
Received: March 29, 2017

Dear Choul-Woo 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,

A handwritten signature in black ink that reads "Robert Ochs". The signature is written in a cursive style and is positioned above a light blue rectangular stamp.

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)

K170930

Device Name

RSM 2430C

Indications for Use (Describe)

The RSM 2430C is a detector indicated for use in screening and diagnostic mammography.

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)

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.

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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)]

03/24/2017

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)]

- Trade Name: RSM 2430C
- Common Name: Digital Flat Panel X-ray Detector
- Classification Name: Full Field Digital, System, X-ray, Mammographic
- Classification Panel: Radiology
- Classification Regulation: 21 CFR 892.1715
- Product Code: MUE
- Device Class: II

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

- 510(k) Number: K162670
- Applicant: DRTECH Corporation
- Trade Name: RSM 1824C
- Classification Name: Full Field Digital, System, X-ray, Mammographic
- Classification Panel: Radiology
- Classification Regulation: 21 CFR 892.1715
- Product Code: MUE
- Device Class: II

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

<Modification>

- Addition of RSM 2430C: The only difference between the subject device and the predicate device is the size of their detectors. This is to notify that RSM 2430C has the exact same functionality and software with the predicate device (K162670) that has been cleared under the 510(k) process.

Items	Subject Device	Predicate Device (K162670)
Model Name	RSM 2430C	RSM 1824C
Detector Size (mm)	240 x 300	180 x 240

The RSM 2430C 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.

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

The intended use has not changed as a result of the modification and is as follows:

The RSM 2430C is a detector indicated for use in screening and diagnostic mammography.

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

The RSM 2430C 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).

Comparisons with the predicate, devices show the technological characteristics of the RSM 2430C to be same to the predicate devices. The RSM 2430C is functionally identical to the predicate devices.

8. Hardware and Software Requirements

- Mammography X-ray System

: Mammography CR System which has 2430 size Bucky.

Contents	Requirement
Bucky Size	Small size(24 x 30) or higher
Grid	Moving
Filter	Mo, Rh (applicable W and Ag)
kVp	20 ~ 35(Mo), 28 ~ 39(Rh)
mAs	3 ~ 500

- Software Requirement

: The product is compatible with Rconsole1 that has been cleared under the 510(k) process (K162670).

9. Substantial Equivalence [21 CFR 807.92(b)]

Parameter	Subject Device	Predicate Device
510(K) Number	Unknown	K162670
Manufacturer	DRTECH Corporation	
Model Name	RSM 2430C	RSM 1824C
Classification Name	Full Field Digital, System, X-ray, Mammographic	
Classification Panel	Radiology	
Classification Regulation	21 CFR 892.1715	
Product Code	MUE	
Device Class	Class II	
Intended Use	The RSM 2430C is a detector indicated for use in screening and diagnostic mammography.	The RSM 1824C is a detector indicated for use in screening and diagnostic mammography.
Pixel Pitch	76 µm	76 µm
Image Size	291.8 x 233.5 mm	233.4 x 175.1mm
Materials Scintillator	CsI	CsI
DQE	43% at 2 lp/mm 30% at 5 lp/mm	43% at 2 lp/mm 30% at 5 lp/mm
MTF	70% @ 2 lp/mm 30% @ 5 lp/mm	70% at 2 lp/mm 30% at 5 lp/mm
Resolution	3,840 x 3,072 (6.1M)	3,072 X 2,304 (6.1M)
Detector Type	TFT a-Si	TFT a-Si
Acquisition devices	Digital X-ray Detector	Digital X-ray Detector

When compared to the predicate devices (K162670), the RSM 1824C presented in this submission has the same:

- Intended Use
- Technological characteristics
- Operating principle
- Materials Scintillator

- Design features
- Performance (DQE, MTF, Resolution)

A few differences are as follows

- Image Size

There is no significant difference between the RMS 2430C 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 and intended use. The difference in the sizes of the detectors only result in the difference in the area that the X-ray images can be taken. Therefore, the difference in the sizes of the detectors does not affect the safety and effectiveness. Also, the results of the clinical image evaluation proved the clinical effectiveness of the subject device.

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

Non-Clinical Performance Testing has been considered according to the IEC 62220-1-2, IEC 61267 and CDRH's Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices.

Test Laboratory	Date of Issue	Report Number	Standard	Test Result
DRTECH	February 1, 2017	DRT-PTR-014	IEC62220-1-2:2007, Medical electrical equipment - Characteristics of digital X-ray imaging devices - Part 1-2: Determination of the detective quantum efficiency - Detectors used in mammography IEC 61267;2005, Medical Diagnostic X-ray Equipment – Radiation Conditions for Use in the Determination of Characteristics	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail

The RSM 2430C 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 62220-1-2: Medical electrical equipment - Characteristics of digital X-ray imaging devices - Part 1-2: Determination of the detective quantum efficiency - Detectors used in mammography
- 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

11. 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 2430C) provide images of equivalent diagnostic capability to the predicate device, RSM 1824C. The results of the study demonstrate substantial equivalence.

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

The RSM 2430C is substantially equivalent to the currently marketed and predicate device (RSM 1824C(K162670)) in terms of design features, fundamental scientific technology, indications for use, and safety and effectiveness.

Additionally, substantial equivalence 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 subject device (RMS 2430C) 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 device is as safe and effectiveness.