January 26, 2023

DRTECH Corporation
% Suyeon Back
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

Re: K220073
Trade/Device Name: RMF-2000
Regulation Number: 21 CFR 892.1715
Regulation Name: Full-field digital mammography system
Regulatory Class: Class II
Product Code: MUE
Dated: December 14, 2022
Received: December 14, 2022

Dear Suyeon Back:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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,

Yanna S. Kang -S

Yanna Kang, Ph.D.
Assistant Director
Mammography and Ultrasound Team
DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices
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)*

K220073

Device Name
RMF-2000

Indications for Use *(Describe)*

The RMF-2000 generates 2D digital mammography images. The RMF-2000 is intended to be used for screening and diagnosis of breast cancer.

This unit is intended for use in the same clinical applications as traditional screen film mammography systems.

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.**

DRTECH

# 510(k) Summary

[As required by 21 CFR 807.92]

K220073

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)]

14/12/2022

## 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-daero541 beon-gil, Jungwon-gu, Seongnam-si, Gyeonggi-do, Republic of Korea
- Contact Name: Suyeon, Back
- Telephone No.: + 82-31-779-7727
- Fax No.: + 82-31-779-7790
- Email Address : syback@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: RMF-2000
- Common Name: Digital Mammography system
- Classification Name: Full Field Digital, System, X-ray, Mammographic
- Classification Panel: Radiology
- Classification Regulation: 21 CFR 892.1725
- Product Code: MUE
- Device Class: II

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

(1) Predicate Device

- 510(k) Number: K110798
- Applicant: GENERAL ELECTRIC COMPANY
- Trade Name: SENOGRAPHE DS
- Classification Name: Full Field Digital, System, X-ray, Mammographic
- Classification Panel: Radiology
- Classification Regulation: 21 CFR 892.1715
- Product Code: MUE
- Device Class: II

(2) Reference Device

- PMA Number: P010025
- Applicant: Hologic, Inc.
- Trade Name: Selenia Dimensions
- 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 Device [21 CFR 807.92(a) (4)]

The system consists of a gantry with integrated high-voltage generator as well as an optional radiation shield with a height-adjustable control desk with an integrated Acquisition Workstation (AWS). The moveable swivel C-arm on the gantry contains the X-ray tube on the top end and the breast support with the X-ray detector on the bottom end. The detector is a full field digital mammography detector.

RMF-2000 acquires digital mammographic images for diagnosis of the breast cancer. RMF-2000 is designed to be used in the same clinical application for 2D screening mammographic systems. The screening examination exposes X-rays to the left and the right breasts of the patient to acquire images. Also, the RMF-2000 can be used to additional precision diagnosis for breasts.

The device's software 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. Indication for Use [21 CFR 807.92(a)(5)]

The RMF-2000 generates 2D digital mammography images. The RMF-2000 is intended to be used for screening and diagnosis of breast cancer.

This unit is intended for use in the same clinical applications as traditional screen film mammography systems.

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

RMF-2000 system is a Full-Field Digital Mammography in which the X-ray film is replaced by proven X-ray detector technology with smallest 76um (indirect) and 65um (direct) pixel size.
With a built-in generator, RMF-2000 is easy to install in small spaces as there is no need for a separate generator compartment.
Using two parameter of thickness and density, which are able to get when a patient takes an x-ray image, according to patient's breast type calculate optimal dose automatically to provide a uniform, high-quality mammogram.
Reliable and precise automatic exposure control perfectly optimizes and determines the exposure parameters in accordance with each patient's breast characteristics with AEC and Dual Filter technology.
Collimator setting is changed automatically for each different paddle type with paddle barcode recognition system.
With the auto-positioning function, the screening protocol set during patient registration is automatically recognized by the system to quickly and easily set the next screening position. The system maintains the patient height information, so no additional height adjustment is required.

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

| Parameter | Subject Device | Predicate Device | Remark |
|---|---|---|---|
| 510(K) Number | Unknown | K110798 | - |
| Manufacturer | DRTECH Corporation | GENERAL ELECTRIC COMPANY | - |
| Model Name | RMF-2000 | SENOGRAPHE DS | - |
| Classification Name | Full Field Digital, System, X-ray, Mammographic | Full Field Digital, System, X-ray, Mammographic | Same |
| Classification Panel | Radiology | Radiology | Same |
| Classification Regulation | 21 CFR 892.1715 | 21 CFR 892.1715 | Same |
| Product Code | MUE | MUE | Same |
| Device Class | Class II | Class II | Same |
| Intended Use | The RMF-2000 generates 2D digital mammography images. The RMF-2000 is intended to be used for screening and diagnosis of breast cancer.<br><br>This unit is intended for use in the same clinical applications as traditional screen film mammography systems. | The Senographe DS and Senographe Essential FFDM systems generate digital mammographic images that can be used for screening and in the diagnosis of breast cancer. The Senographe DS and Senographe Essential FFDM systems are intended to be used in the same clinical applications as traditional film-based mammographic systems. | Same |
| Patient population | Age : Adult for the purpose of mammography screening | Age : Adult for the purpose of mammography screening | Same |
| Design | Detector Size : 240 x | Detector Size : 240 x | Same |

| | | | |
|---|---|---|---|
| | 300mm | 300mm | |
| | Pixel Pitch<br>-RSM 2430UDP: 65um<br>-RSM 2430TD: 76um | Pixel Pitch<br>100um | Higher: Pixel pitch is smaller than predicate device |
| | Resolution<br>-RSM 2430 UDP: 4,608 x 3,584<br>-RSM 2430TD: 3,840 x 3,072 | Resolution<br>2,294 x 1,914 | Higher |
| Materials Scintillator | RSM 2430 UDP (Selenium)<br>RSM 2430TD (CsI) | CsI | Same or Higher |
| Detector Type | RSM 2430 UDP: a-Se<br>RSM 2430TD : amorphous silicon with CsI scintillator | CsI | Same or Higher: Wide input voltage range RMF-2000 complies with IEC60601-1 and IEC60601-2-45. |
| Power supply | Single-Phase, Input voltage 200-240 Vac (±10%) | Single-phase input voltage: 200/208/220/240 V (±10%) | Higher: Wide input voltage range RMF-2000 complies with IEC60601-1 and IEC60601-2-45. |
| Exposure mode | AEC (Automatic Exposure Control), Manual | AOP (Automatic Optimization of Parameters) Manual | Same, AEC and AOP are calculate optimized X-ray exposure parameter |
| Generator Type | High Frequency | High Frequency | Same |
| Breast Compression System | Maximum Compression that can be applied (N)<br>Motor driven: 200<br>Manual: 30 | Maximum Compression that can be applied (N)<br>Motor driven: 200<br>Manual: 30 | Same |

| | | | |
|---|---|---|---|
| SID | 660mm | 660mm | Same |
| DICOM | DICOM Services, SCU, Storage Commitment, MPPS, worklist management SCU, structured report, media storage, print | DICOM Services, SCU, Storage Commitment, MPPS, worklist management SCU, structured report, media storage, print | Same |

The predicate device (K110798) and the subject device, RMF-2000 are equivalent in terms of the following matters:

- Intended Use
- Patient population
- Detector size
- Exposure mode
- Generator Type
- Breast Compression System
- SID
- DICOM

A few differences are as follows

- Pixel Pitch
- Resolution
- Materials Scintillator
- Detector Type
- Power supply

There is no significant difference between the RMF-2000 and the predicate device that would adversely affect the use of the product. The subject device is substantially equivalent to the predicate device.

Even though the predicate device and the subject device differ, 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.

| Parameter | | Subject Device | Reference Device | Remark |
|---|---|---|---|---|
| Manufacturer | | DRTECH Corporation | Hologic | - |
| Model Name | | RMF-2000 | Selenia Dimensions | - |
| PMA Number | | - | P010025 | - |
| Classification Name | | Full Field Digital, System, X-ray, Mammographic | | Same |
| Classification Panel | | Radiology | | Same |
| Classification Regulation | | 21 CFR 892.1715 | | Same |
| Product Code | | MUE | | Same |
| Device Class | | Class II | | Same |
| Intended Use | | The RMF-2000 generates 2D digital mammography images. The RMF-2000 is intended to be used for screening and diagnosis of breast cancer.<br><br>This unit is intended for use in the same clinical applications as traditional screen film mammography systems. | The Hologic Selenia Dimensions generates digital mammographic images that can be used for screening and diagnosis of breast cancer. The Selenia Dimensions system is intended for use in the same clinical applications as Full Field Digital Mammography systems for screening mammograms. | Same |
| Design | Detector Size | 240 x 300mm | 240 x 290mm | Same or Higher |
| | Pixel Pitch | 65um | 70um | Same or Higher |
| | Resolution | 4,608x 3,584 | 3,328x 4,096 | Same or Higher |
| Materials Scintillator | | a Se direct.<br>RSM 2430 UDP (Selenium) | a Se direct. | Same |
| TFT | | Amorphous Selenium | Amorphous Selenium | Same |

| | | | |
|---|---|---|---|
| Exposure mode | AEC (Automatic Exposure Control), Manual | AEC (Automatic Exposure Control), Manual | Same |
| Anatomical Sites | Breast | Breast | Same |
| Communication Method | Wire | Wire | Same |

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

The RMF-2000 introduces no new safety or efficacy issues other than those already identified with the predicate device. To demonstrate the safety and effectiveness of RMF-2000 and to demonstrate substantial equivalence to the predicate device, RMF-2000 has completed the following non-clinical tests. This confirms that the design inputs and performance specifications of this equipment have been met. The RMF-2000 has been tested according to internal requirements, national standards and international standards indicated below to support safety and effectiveness and substantial equivalence to predicate device.
The RMF-2000 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 4) |
| ISO 14971: | Medical Devices - Application of Risk Management to Medical Devices. (Second edition) |
| IEC 60601-2-45: | Medical electrical equipment - Part 2-45: Particular requirements for the basic safety and essential performance of mammographic X-ray equipment and mammographic stereotactic devices (Edition 3.1) |
| IEC 62304: | Medical device software - Software life cycle processes |
| IEC 60601-1-3: | Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment (Edition 2.1) |
| IEC 60601-1-6: | Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability |
| 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 |
| ISO 10993-1: | Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process |
| ISO 10993-5: | Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (Third edition) |
| ISO 10993-10: | Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization (Third edition) |
| ISO 15223-1: | Symbols to be used with medical device labels, labeling and information to be supplied |

And RMF-2000 complies with the FDA guidance document entitled ‘Class II Special Controls Guidance Document: Full-Field Digital Mammography System,’ March 27, 2012.

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

A clinical image evaluation in accordance with the Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Full Field Digital Mammography System issued on April 4, 2012 (Section 9 Clinical Image Evaluation) was conducted with the RMF-2000 and determined that the images, reviewed by MQSA qualified interpreting physicians, were of sufficiently acceptable quality for mammographic usage and that the images are substantially equivalent to those from predicate device.

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

The RMF-2000 is substantially equivalent to the currently marketed predicate device in terms of design, fundamental scientific technology, and indications for use, safety, and effectiveness.

Substantial equivalence for Digital Mammography system (RMF-2000) 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 60601-2-45, IEC 62304, IEC 60601-1-3, IEC 60601-1-6, IEC 62220-1-2, AAMI ANSI ISO 10993-1, ISO 10993-5, and ISO 10993-10.

Also, substantial equivalence was demonstrated through a clinical test, which was conducted in accordance with in the "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 RMF-2000 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 RMF-2000 is substantially equivalent to the predicate device.