May 28, 2026

Vieworks Co., Ltd.
Seonghwan Park
Regulatory Affairs Assistant Manager
41-3, Burim-Ro 170beon-Gil, Dongan-Gu
ANYANG-SI, GYEONGGI-DO, 14055
REPUBLIC OF KOREA

Re: K254092
Trade/Device Name: Bellalun 2D (VDMS-1000S)
Regulation Number: 21 CFR 892.1715
Regulation Name: Full-Field Digital Mammography System
Regulatory Class: Class II
Product Code: MUE
Dated: April 29, 2026
Received: April 29, 2026

Dear Seonghwan Park:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

YANNA S. KANG -S

Yanna Kang, Ph.D.
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K254092

Device Name
Bellalun 2D (VDMS-1000S)

Indications for Use *(Describe)*
VDMS-1000S is intended for generating mammographic images that can be used for screening and diagnosis of breast cancer. It can be used to acquire 2D digital mammograms in the same clinical applications as traditional film/screen 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.

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510(k) Summary (K254092)

This 510(k) summary information is prepared in accordance with 21 CFR 807.92

1. Date Prepared [21 CFR 807.92(a) (1)]

11/28/2025

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

Name of Sponsor:	Vieworks Co., Ltd.
Address:	41-3, Burim-ro 170beon-gil, Dongan-gu, Anyang-si, Gyeonggi-do, 14055 Republic of Korea
Contact Name:	Seonghwan Park / Regulatory Affairs Assistant Manager
Telephone	+82-70-7751-9602
Registration Number:	3006013411
Name of Manufacturer:	Same as Sponsor

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

Trade Name:	Bellalun 2D (VDMS-1000S)
Common Name:	Digital Mammography System
Classification Name:	Full Field Digital, System, X-Ray, Mammographic
Classification Panel:	Radiology
Classification Regulation:	21 CFR 892.1715
Product Code:	MUE
Device Class:	2

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

510(k) Number:	**K220073**
Applicant:	DRTECH Corporation
Trade Name:	RMF-2000
Common Name:	Digital Mammography System
Classification Name:	Full-Field Digital Mammography System
Classification Panel:	Radiology
Classification Regulation:	21 CFR 892.1715
Product Code:	MUE
Device Class:	2
Decision Date:	01/26/2023
Type:	Traditional

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

- General Description

The device is composed of a gantry—which includes a high-voltage generator, X-ray tube assembly, collimator, and digital detector—along with a console table and accessories such as a foot switch, compression paddle, and magnification stand. It is intended for use in diagnostic mammography.
The image signals generated by X-ray exposure are converted into digital signals and stored in the workstation (console table). Various image processing algorithms are applied through software to achieve optimal image quality. In addition, the device complies with the international medical imaging standard, DICOM (Digital Imaging and Communications in Medicine), to support integration with PACS.

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

VDMS-1000S is intended for generating mammographic images that can be used for screening and diagnosis of breast cancer. It can be used to acquire 2D digital mammograms in the same clinical applications as traditional film/screen systems.

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

Comparisons with the predicate, devices show the technological characteristics of the proposed VDMS-1000S device to be substantially equivalent to the predicate devices. The proposed devices are functionally identical to the predicate devices.

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

When compared to the predicate devices (**K220073**), the VDMS-1000S presented in this submission has the substantially equivalent:

- Indications for Use
- Patient Population
- Design
- Materials Scintillator
- Detector Type
- Power supply
- Exposure Mode
- Generator Type
- Breast Compression System
- SID

There are no significant difference between the VDMS-1000S and the predicate device that would adversely affect the use of the product. It is substantially equivalent to these devices in design, function, materials, operational principles and intended use.

Parameter	Predicate Device	Subject Device	Equivalence
510(k) Number	K220073	-	-
Manufacturer	DRTECH Corporation	Vieworks Co., Ltd.	-
Model Name	RMF-2000	VDMS-1000S	-
Classification Name	Full Field Digital, System, X-ray, Mammographic		Equivalent
Classification Panel	Radiology		Equivalent
Classification Regulation	21 CFR 892.1715		Equivalent
Product Code	MUE		Equivalent
Device Class	2		Equivalent
Indications for Use	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.	VDMS-1000S is intended for generating mammographic images that can be used for screening and diagnosis of breast cancer. It can be used to acquire 2D digital mammograms in the same clinical applications as traditional film/screen systems.	Substantially Equivalent
Patient Population	Age: Adult for the purpose of mammography screening	Age: VDMS-1000S is used to examine adult patients, mainly female patients older than 40 years old.	Equivalent
Design	Detector Size: 240 x 300 mm	Detector Size: 254.5 x 327.5 mm	Substantially Equivalent
	Pixel Pitch -RSM 2430UDP: 65um -RSM 2430TD: 76um	Pixel Pitch -FXMD-2430DAH: 75um	Substantially Equivalent
	Resolution -RSM 2430UDP: 4,608 x3,584 -RSM 2430TD: 3,840 x 3,072	Resolution -FXMD-2430DAH: 3,840 x 3,072	Substantially Equivalent

Materials Scintillator	RSM 2430UDP (Selenium) RSM 2430TD (CsI)	FXMD-2430DAH (CsI)	Substantially Equivalent
Detector Type	RSM 2430UDP: a-Se RSM 2430TD: amorphous silicon with CsI scintillator	FXMD-2430DAH: amorphous silicon TFT with Photo diode	Substantially Equivalent
Power supply	Single-Phase, Input voltage 200-240 Vac (±10%)	Single-Phase, Input voltage 220-240 Vac	Substantially Equivalent
Exposure Mode	AEC (Automatic Exposure Control), Manual	Semi-Auto, Auto, Manual	Substantially Equivalent
Generator Type	High Frequency	High Frequency	Equivalent
Breast Compression System	Maximum Compression that can be applied (N) Motor driven: 200 Manual: 30	Maximum Compression that can be applied (N) Motor driven: 200 Manual: 50	Substantially Equivalent
SID	660 mm	650 mm	Substantially Equivalent

9. Summary of Non-Clinical Data

A comparison test was conducted between the subject devices VDMS-1000S and the predicate device (**K220073**) on the items such as DQE, MTF.

These detectors comply with the following international and FDA-recognized consensus standards:

- IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007) + A2: 2020
- Notification of MFDS No. 2025-06, Annex 1 (includes National Differences for Korea)
- IEC 60601-1-6: 2010 (Third Edition) + A2: 2020
- IEC 60601-1-2:2020
- IEC 60601-2-45:2011 + A2:2022

10. Summary of Clinical Data

A clinical image evaluation according to CDRH's 'Guidance for Industry and FDA Staff – Class II Special Controls Guidance Document: Full Field Digital, System, X-ray, Mammographic was conducted, and the study confirmed that the subject device provides images of equivalent diagnostic capability to the predicate devices, RMF-2000 and its results demonstrate substantial equivalence.

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

The VDMS-1000S Digital Mammography System is substantially equivalent to the currently marketed and predicate device (K220073) in terms of Indications for Use, Patient Population, Design, Materials Scintillator, Detector Type, Power supply, Exposure Mode, Generator Type, Breast Compression System, SID and safety and effectiveness.

Additionally, Substantial equivalence was demonstrated through the non-clinical performance, which complied with the requirements specified in the international and FDA-recognized consensus standards, IEC60601-1, IEC 60601-1-2, IEC 60601-2-45 and the clinical test, which complied with the requirements specified in the CDRH's 'Class II Special Controls Guidance Document: Full Field Digital, System, X-ray, Mammographic.

The results of these tests demonstrate that VDMS-1000S Digital Mammography System meets the acceptance criteria and is adequate for this intended use. The comparison of technological characteristics, non-clinical performance data, safety testing, and clinical image concurrence data demonstrates that the device is as safe, and effective as the predicate device.