March 26, 2026

Airs Medical, Inc.
Markus Cho
RA Manager
13-14f, Keungil Tower, 223, Teheran-Ro, Gangnam-Gu
Seoul, Seoul 06142
Republic Of Korea

Re: K253775
Trade/Device Name: SwiftMR
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: February 27, 2026
Received: February 27, 2026

Dear Markus Cho:

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,

Daniel M. Krainak, Ph.D.
Assistant Director
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K253775

Device Name
SwiftMR

Indications for Use *(Describe)*
SwiftMR is a stand-alone medical imaging software solution intended for the acceptance, enhancement, processing, review, analysis, communication, and transfer of all body parts MR images in DICOM format. The software may be used for the enhancement of medical images, such as noise reduction and increased image sharpness for MR images.

The device is designed for use by healthcare professionals and is intended to assist clinicians, who remain responsible for making all final patient management decisions. The device is not intended for use on mobile devices.

The available field strengths are as follows: 0.25T, 0.31T, 0.4T, 0.55T, 0.6T, 1.5T, and 3.0T.

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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

K253775

This 510(k) Summary of safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

I. SUBMITTER

Mr. Markus Cho
RA Specialist
AIRS Medical Inc.
13-14F, Keungil Tower, 223, Teheran-ro, Gangnam-gu,
Seoul, 06142, Republic of Korea
Phone: +82-10-3974-4600
FAX: +82-2-6280-3185
Email: cho.markus@airsmed.com

Date Prepared: March 23, 2026

II. DEVICE

Name of Device: SwiftMR
Common or Usual Name: Medical Image Management and Processing System
Classification Name: system, image processing, radiological (21 CFR 892.2050)
Regulatory Class: II
Product Code: QIH

III. PREDICATE DEVICE

Predicate Device: SwiftMR – K230854 by AIRS Medical, Inc., Class II, CFR 892.2050, classification with product code LLZ.

IV. DEVICE DESCRIPTION

SwiftMR is software used as a Medical Device (SaMD) consisting of a software algorithm that enhances images taken by MRI scanners. The device only processes DICOM images for the end user and is intended to be used by radiology technologists in an imaging center, clinic, or hospital.

The device's inputs are MRI images in DICOM format. The deep learning algorithm produces enhanced images as outputs with reduced noise and increased sharpness in DICOM format. The deep learning algorithm performs noise reduction with the ability of adjusting the denoising level from level 0 to level 8, and sharpening filter performs the sharpening function with the ability of adjusting the sharpness level from level 0 to level 5.

SwiftMR provides an automatic image quality enhancement function for MR images acquired in various environments. SwiftMR can only be used for professional purposes and is not intended for use on mobile devices.

SwiftMR's automation procedure is as follows:

- Receive MR images that are in DICOM format from PACS or from MRI
- Image quality enhancement using Deep Learning model and sharpening filter
- Transfer enhanced MR image as DICOM format to PACS or to MRI

SwiftMR supports input images reconstructed using both conventional vendor reconstruction algorithms and vendor-implemented deep learning (DL) reconstruction pipelines. These vendor DL-reconstructed images are treated as standard DICOM images, and compatibility verification has confirmed that upstream DL processing does not negatively affect SwiftMR performance, artifacts, or anatomical fidelity.

Image Enhance deep leaning model can be applied to MR images with field strengths of 0.25T, 0.31T, 0.4T, 0.55T, 0.6T, 1.5T, and 3.0T. SwiftMR is compatible with both conventional vendor reconstruction methods and vendor-implemented deep learning reconstruction pipelines.

At the same time, SwiftMR allows logged-in users to use its functions and view the processing status. When logged in as the System Admin, the function is available to control automation procedure and system change settings. On the User side, the User can retrieve the results of image processing in the form of a worklist by login to the user account.

The software provides three main functions, which are image processing, quality check and progress monitoring. As part of the image processing functionality, the software performs the following non-deep-learning processing of MR images:

- Diffusion-related processing: ADC, exponential ADC, calculated b-value, fractional anisotropy (FA), FA color, tractography
- Perfusion-related processing: cerebral blood flow, cerebral blood volume, mean transit time, time to peak
- Susceptibility-weighting imaging related processing: filtered phase, phase mask weighting
- 3D-related processing: Maximum Intensity Projection (MIP), Minimum Intensity Projection (minIP), Multi-Planar Reconstruction (MPR)

The software is intended to run automatically in the background so that it does not interrupt the workflow of users. When the user executes MR scans as he/she usually does, the newly acquired images are automatically uploaded to the server and registered in the database (DB) for image processing. Once image processing is complete, the images are sent to PACS or to MR device.

If the user wishes to monitor this automated workflow to check on the status of image processing, he/she can check the main page of the client application or toast messages will appear on the bottom right corner upon completion of each processing. After using the software, they should log out for security reasons.

A settings menu is provided in the form of a user interface to enable the system admin to modify software settings as required by the institution or respective user.

V. INDICATIONS FOR USE

SwiftMR is a stand-alone medical imaging software solution intended for the acceptance, enhancement, processing, review, analysis, communication, and transfer of all body parts MR images in DICOM format. The software may be used

for the enhancement of medical images, such as noise reduction and increased image sharpness for MR images.

The device is designed for use by healthcare professionals and is intended to assist clinicians, who remain responsible for making all final patient management decisions. The device is not intended for use on mobile devices.

The available field strengths are as follows: 0.25T, 0.31T, 0.4T, 0.55T, 0.6T, 1.5T, and 3.0T.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

The subject device and the predicate devices are substantially equivalent in the areas of general function, application, and intended use.

Any differences between the predicate and the subject device have no negative impact on the device safety or efficacy and does not raise any new potential or increased safety risks and is equivalent in performance to existing legally marketed devices.

Item	Subject Device (SwiftMR)	Predicate Device #1 (SwiftMR (K230854))	Differences
Regulation number / Classification	21 CFR 892.2050 / Class II	21 CFR 892.2050 / Class II	Equivalent
Product code	QIH	LLZ	Equivalent under same regulation number
Indication for use	SwiftMR is a stand-alone medical imaging software solution intended for the acceptance, enhancement, processing, review, analysis, communication, and transfer of all body parts MR images in DICOM format. The software may be used for the enhancement of medical images, such as noise reduction and increased image sharpness for MR images. The device is designed for use by healthcare professionals and is intended to assist	SwiftMR is a stand-alone software solution intended to be used for acceptance, enhancement and transfer of all body parts MR images in DICOM format. It can be used for noise reduction and increasing image sharpness for MR images. SwiftMR is not intended for use on mobile devices.	Equivalent The subject device is substantially equivalent to the primary predicate, SwiftMR (K230854), as they share the same intended use and core technological principles for MR image processing.

	clinicians, who remain responsible for making all final patient management decisions. The device is not intended for use on mobile devices. The available filed strengths are as follows: 0.25T, 0.31T, 0.4T, 0.55T, 0.6T, 1.5T, and 3.0T.		
Input data	MR images in DICOM format	MR images in DICOM format	Equivalent (MR input consistent with both predicates)
Output	Enhanced / processed MR images in DICOM	Enhanced MR images in DICOM	Equivalent
Intended users	Healthcare professionals; final clinical responsibility remains with clinician	Same	Equivalent
Intended environment	Healthcare environment	Healthcare environment	Equivalent
Enhancement	Noise reduction and increased sharpness	Same (noise reduction, sharpening)	Equivalent to Predicate device #1 (K230854)

VII. PERFORMANCE DATA

SwiftMR, has been assessed and tested and has passed all predetermined testing criteria. The Validation Test Plan was designed to evaluate output functions.

Validation testing indicated that as required by the risk analysis, designated individuals performed all verification and validation activities and that the results demonstrated that the predetermined acceptance criteria were met.

The following tests were conducted for SwiftMR:

1) Verification testing: Unit test, system test conducted. These tests passed.
2) Validation testing: Performance test was conducted using retrospective clinical images for both noise reduction and sharpness increase functions.
   A. For the noise reduction performance, acceptance criteria were defined that the average signal-to-noise ratio (SNR) of the SwiftMR-processed image series is increased by 40% or more for at least 90% of the dataset for level 1 with an incremental 1% increase per each level. This test passed.
   B. For the sharpness increase performance, acceptance criteria were defined that the FWHM of a selected region of interest (ROI) is decreased by 0.13% (deep learning model), 0.43% (filter level 1), 1.7% (filter level 2), 2.3% (filter level 3), 3.6% (filter level 4), 4.5% (filter level 5) or more for at least 90% of the dataset. This test passed.

The validation dataset consists of data of the following conditions:

1. Manufacturer: SIEMENS, GE, PHILIPS, CANON, ESAOTE, FONAR, FUJIFILM
2. Field Strength: 0.25T / 0.31T / 0.4T / 0.55T / 0.6T / 1.5T / 3.0T

3. Anatomical region: Body (breast, abdomen, and pelvis), Cardiac, Neuro (head, neck, and spine), Musculoskeletal (shoulder, wrist, hip, knee, and ankle)
4. Protocol: T1, T2, T2*, FLAIR, PD, DWI, MRA
5. Demographics
- age: Adults (22~93 yrs, 91.1%), Pediatrics (0~21 yrs, 8.9%)
- gender: Male (48.4%), Female (41.2%), Other (10.4%)
6. Time reduction range for reduced scan time images: up to 50%
7. Image reconstruction: Conventional (81.2%), Deep Learning Reconstructed (18.8%)

To show that the performance of the device is not hindered by site variability, in the validation dataset, we included data from sources not included in the training dataset.

Therefore, it was demonstrated that SwiftMR performance was shown to be substantially equivalent to the predicate device.

VIX. CONCLUSION

The information presented in the 510(k) for SwiftMR contains adequate information, data, and nonclinical test results to demonstrate substantial equivalence to the predicate device. SwiftMR was shown to be substantially equivalent to the predicate device in the areas of technical characteristics, general function, application, and does not raise different questions of safety and effectiveness.