July 24, 2026

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

Re: K261349
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: June 3, 2026
Received: June 3, 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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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,

NINGZHI LI -S Digitally signed by NINGZHI LI -S

for
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261349

Please provide the device trade name(s).

SwiftMR

Please provide your Indications for Use below.

SwiftMR is a stand-alone medical imaging software solution intended for the acceptance, enhancement, processing, review, analysis, communication, and transfer of MR images in DICOM format. The software may be used for the enhancement of medical images, such as noise reduction and increased image sharpness, as well as for image processing, such as segmentation to remove background anatomy for Maximum Intensity Projection (MIP) visualization.

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.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☒ Neonates/Newborns (Birth to < 29 days old) ☒ Infants (29 days old to < 2 years old) ☒ Children (2 years old to < 12 years old) ☒ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) Summary

K261349

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

I. SUBMITTER

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RA Specialist
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Date Prepared: May 21th, 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 – K253775 by AIRS Medical, Inc., Class II, CFR 892.2050, classification with product code QIH.

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

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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 includes an MIP Auto-cutting feature that uses deep learning segmentation of anatomical structures to facilitate automated removal/cropping of non-target tissues during MIP generation. This functionality is intended to assist clinicians; users remain responsible for all final image review and patient-management decisions.

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.

510(k) Summary

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 MR images in DICOM format. The software may be used for the enhancement of medical images, such as noise reduction and increased image sharpness, as well as for image processing, such as segmentation to remove background anatomy for Maximum Intensity Projection (MIP) visualization.

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 device 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 (SwiftMR (K253775))	Differences
Regulation number / Classification	21 CFR 892.2050 / Class II	21 CFR 892.2050 / Class II	Equivalent
Product code	QIH	QIH	Equivalent
Indication for use	SwiftMR is a stand-alone medical imaging software solution intended for the acceptance, enhancement, processing, review, analysis, communication, and transfer of MR images in DICOM format. The software may be used for the enhancement of medical images, such as noise reduction and	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	Equivalent The subject device is substantially equivalent to the primary predicate, SwiftMR (K253775), as they share the same intended use and core technological principles for MR image processing.

	increased image sharpness, as well as for image processing, such as segmentation to remove background anatomy for Maximum Intensity Projection (MIP) visualization. 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.	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.	While the predicate device focuses on image enhancement through noise reduction and sharpening, the subject device extends this logic to include MIP Auto-cutting. This feature is fundamentally aligned with the predicate's established principle of improving image visualization; whereas the predicate improves quality at the pixel level (SNR/FWHM), the MIP Auto-cutting feature improves visualization at the structural level by removing background interference. Since both the subject device and the predicate are intended to enhance the diagnostic quality of MR images through automated processing—and because the subject device maintains the exact same rigorous performance criteria as the cleared predicate—no new questions of safety or effectiveness are introduced.
Input data	MR images in DICOM format	MR images in DICOM format	Equivalent
Output	Enhanced / processed MR images in DICOM	Enhanced MR images in DICOM	Equivalent
Intended users	Healthcare professionals; final clinical responsibility remains with clinician	Healthcare professionals; final clinical responsibility remains with clinician	Equivalent
Intended environment	Healthcare environment	Healthcare environment	Equivalent

Image Enhancement	Noise reduction and increased sharpness and MIP Auto Cutting	Noise reduction, increased sharpness	Equivalent The subject device is substantially equivalent to the predicate (K253775), sharing the same intended use and core image enhancement principles. While maintaining identical pixel-level enhancement (SNR/FWHM), the subject device adds MIP Auto-cutting to improve structural visualization by removing background interference. This independent functional module follows the same rigorous performance criteria as the cleared predicate and introduces no new questions of safety or effectiveness

This submission is being made to obtain clearance for the addition of the MIP Auto Cutting feature to the previously cleared device.

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%)

The training dataset for the Image Enhancement model was collected from institutions in the Republic of Korea across three scanner manufacturers.

Image Enhancement Model — Training Dataset
Siemens (Total: 12,000 subjects)

Institution	Cases
Seoul National University Hospital	10,000
Seoul Asan Hospital	500
Korea Medical Institute	1,500

Anatomical regions: Neuro (5,000), MSK (4,000), Body (3,000)
Age: 3–95 years
Gender: Male 50.2%, Female 49.8%
Pulse sequences — Neuro: T1, T2, T2*, FLAIR, DWI, MRA / MSK: T1, T2, T2*, PD / Body: T1, T2, DWI

GE (Total :9,000 subjects)

Institution	Cases
Human Medical Imaging	4,000
We Want Healthcare	4,000
Seoul National University Hospital	1,000

Anatomical regions: Neuro (5,500), MSK (3,000), Body (500)
Age: 11–93 years
Gender: Male 50.2%, Female 49.8%
Pulse sequences — Neuro: T1, T2, T2*, FLAIR, DWI, MRA / MSK: T1, T2, T2*, PD / Body: T1, T2, DWI
Phillips (Total : 9,400 subjects)

Institution	Cases
Yeson Hospital	4,000
Seoul National University Hospital	5,400

Anatomical regions: Neuro (4,900), MSK (2,500), Body (2,000)
Age: 15–67 years

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Gender: Male 49.9%, Female 50.1%
Pulse sequences — Neuro: T1, T2, T2*, FLAIR, DWI, MRA / MSK: T1, T2, T2*, PD / Body: T1, T2, DWI

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.

For the MIP Auto-Cutting function, performance was verified on retrospective datasets of actual MR imaging studies of patients. A total of 78 imaging studies were used to evaluate the device. No dataset contained more than one imaging study from any particular patient. No imaging study used to verify performance was used for training; independence of training and testing data were enforced at the level of the scanning institution, namely, studies sourced from a specific institution were used for either training or testing but could not be used for both. The data used in the device validation ensured diversity in patient population and scanner manufacturers. Subgroup analysis was performed for patient age, patient sex, and scanner manufacturers. Verification datasets included 54% female patients and 46% male patients. Across all datasets, 69.2% of patients were adults, 24.4% were pediatric, and 6% were of unknown age. Scanner manufacturers included GE Medical Systems, Siemens, Philips, Canon, Fonar, Fujifilm, ASG, and Esaote. Ethnicity of patients in the datasets was reasonably correlated to the overall US population.

Performance was verified by comparing segmentations generated by the machine learning models against segmentations generated by medical professionals from the same imaging study. The performance of the machine learning models, characterized by the Sørensen–Dice coefficient (DSC) was as follows: Head 0.98 DSC; Neck 0.98 DSC and at least 90% of the cases demonstrated an HD-95 of ≤ 14mm.

MIP Auto-Cutting Model — Training Dataset

Vendor

Vendor	Cases
Siemens	500
GE	500
Phillips	500

Institution (Total 1,500 subjects)

Institution	Cases
Seoul National University Hospital	500
Yeson Hosptial	400
WeWant Healthcare	400
Human Medical Imaging	200

Anatomical regions: Head (750) and Neck (750)

Image Type: MR Angiography(1500)

Age: 3-92 years old

Gender: Male 54%, Female 46%

Ground truth segmentation masks for the MIP Auto-Cutting model were generated by three board-certified radiologists in the United States. Annotation disagreements were resolved through a consensus-based adjudication process.

Training data independence from the validation dataset was ensured at the institution level; data sourced from a specific institution was used exclusively for either training or validation.

The accuracy of measurement features has been validated on datasets of actual MR imaging studies of patients.

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.