



September 23, 2025

AIRS Medical Inc.
HaeRi Lee
RA Manager
13-14F, Keungil Tower, 223, Teheran-ro, Gangnam-gu
Seoul, 06142
Republic of Korea

Re: K251483
Trade/Device Name: SwiftSight-Brain
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QIH, LLZ
Dated: August 25, 2025
Received: August 25, 2025

Dear HaeRi Lee:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 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 systems (QS) regulation (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,

A handwritten signature in black ink, appearing to read 'D. Krainak', is written over a large, light blue, semi-transparent 'FDA' watermark.

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

510(k) Number (if known)

K251483

Device Name

SwiftSight-Brain

Indications for Use (Describe)

This device is intended for automatic labelling, visualization and volumetric quantification of segmentable brain structures and lesions from a set of MR images. Volumetric data may be compared to reference percentile data.

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.

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Date of the 510(k) summary preparation: September 18th, 2025

510(k) Summary

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

1. Submitter

- Name: AIRS Medical Inc.
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- Phone: +82-10-4820-5200
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2. Contact person

- Name: HaeRi Lee
- Position: RA Manager
- Email: lee.haeri@airsmmed.com

3. Device information

- Device trade name: SwiftSight-Brain
- Model name: SS25-BR-CL
- Primary product specifications
 - Regulation No. 21 CFR 892.2050
 - Device class: Class II
 - Product code: QIH
 - Classification name: Automated radiological image processing software
- Associated product specifications
 - Regulation No. 21 CFR 892.2050
 - Device class: Class II
 - Product code: LLZ
 - Classification name: System, image processing, radiological

4. Predicate device

- Device trade name: Neurophet AQUA (V3.1)
- 510(k) number: K242215
- Product specification
 - Regulation No. 21 CFR 892.2050
 - Classification: Class II
 - Product code: QIH, LLZ

5. Device description

SwiftSight-Brain is a fully automated MR image analysis software that provides automatic labeling, visualization, and volumetric quantification of brain structures from a set of MR images and

returns segmented images and morphometric reports. The resulting output is provided in morphometric reports that can be displayed on Picture Archive and Communications Systems (PACS). The high throughput capability makes the software suitable for use in routine patient care as a support tool for clinicians in assessment of structural MRIs.

SwiftSight-Brain provides morphometric measurements based on 3D T1 weighted MRI series. The output of the software includes volumes that have been annotated with color overlays, with each color representing a particular segmented region, and morphometric reports that provide comparison of measured volumes to age and gender-matched reference percentile data. In addition, the adjunctive use of the T2 weighted FLAIR MR series allows for improved identification of some brain abnormalities such as lesions, which are often associated with T2 weighted FLAIR hyperintensities.

SwiftSight-Brain processing architecture includes a proprietary automated internal pipeline that performs segmentation, volume calculation and report generation.

The results are displayed in a dedicated graphical user interface, allowing the user to:

- Browse the segmentations and the measures
- Compare the results of segmented brain structures to a reference healthy population
- Read, download and print a PDF report

Additionally, automated safety measures include automated quality control functions, such as scan protocol verification, which validate that the imaging protocols adhere to system requirements.

6. Indications for Use

This device is intended for automatic labelling, visualization and volumetric quantification of segmentable brain structures and lesions from a set of MR images. Volumetric data may be compared to reference percentile data.

7. Comparison of technological characteristics with the predicate device

The table below compares SwiftSight-Brain (subject device) with Neurophet AQUA V3.1 (predicate device, K242215).

Comparison table

	Subject device	Predicate device	Substantial Equivalence
Device name	SwiftSight-Brain	Neurophet AQUA V3.1	-
510(k)	-	K242215	-
Manufacturer	AIRS Medical Inc.	NEUROPHET, Inc	-
Product code	QIH, LLZ	QIH, LLZ	Same
Indications for use	This device is intended for automatic labelling, visualization and volumetric quantification of segmentable brain structures and lesions from a set of MR images. Volumetric data may be	Neurophet AQUA is intended for automatic labeling, visualization and volumetric quantification of segmentable brain structures and lesions from a set of MR images. Volumetric data may be compared to reference	Same

	Subject device	Predicate device	Substantial Equivalence
	compared to reference percentile data.	percentile data.	
Target anatomical sites	Brain	Brain	Same
Design and incorporated technology	- Automated measurement of brain tissue volumes, structures, and lesions - Automatic segmentation and quantification of brain structures using deep learning	- Automated measurement of brain tissue volumes, structures, and lesions - Automatic segmentation and quantification of brain structures using deep learning	Same
Physical characteristics	- Software package - Operates on off-the shelf hardware (multiple vendors)	- Software package - Operates on off-the shelf hardware (multiple vendors)	Same
Operation system	Windows	Windows	Same
Processing architecture	Automated internal pipeline that performs: - segmentation - volume calculation - report generation	Automated internal pipeline that performs: - segmentation - volume calculation - report generation	Same
Data source	- MRI scanner: 3D T1 and FLAIR MRI scans acquired with specified protocols - Supports DICOM format as input	- MRI scanner: 3D T1 and FLAIR MRI scans acquired with specified protocols - Supports DICOM format as input	Same
Output	- Provides volumetric measurements of brain structures and lesions - Includes segmented color overlays and morphometric reports - Automatically compares results to reference percentile data and to prior scans when available - Supports DICOM format as output of results that can be displayed on DICOM workstations and Picture Archive and Communications Systems	- Provides volumetric measurements of brain structures and lesions - Includes segmented color overlays and morphometric reports - Automatically compares results to reference percentile data and to prior scans when available - Supports DICOM format as output of results that can be displayed on DICOM workstations and Picture Archive and Communications Systems	Same
Safety	Automated quality control functions	Automated quality control functions	Substantially Equivalent

	Subject device	Predicate device	Substantial Equivalence
	- Tissue contrast check - Scan protocol verification • Results must be reviewed by a medical professional	- Image artifact check - Scan protocol verification • Results must be reviewed by a trained physician	

SwiftSight-Brain and the predicate device are identical in most aspects, including intended use, target anatomical site, physical characteristics, processing architecture, data source, and output. While there are differences in terminology related to the automated quality control function and the user who reviews the results, these differences do not affect safety or effectiveness, do not introduce new or increased safety risks, and demonstrate equivalent performance to existing legally marketed devices

8. Summary of non-clinical test

The software verification and validation tests were conducted to establish the performance, functionality and reliability characteristics of the subject devices. The device passed all the tests based on pre-determined Pass/Fail criteria.

To demonstrate the 3D T1 weighted and T2 weighted FLAIR analysis performance of the SwiftSight-Brain, the data primarily sourced from U.S. hospitals were utilized. The data presents a diverse mix of clinical, demographic, and technical variables, providing a foundation for both reliable and reproducible testing, as well as comprehensive accuracy assessment. The ground truth was established by the U.S. based two neuroradiologists and one neurologist. The multi-site data collection enhances statistical independence, while the inclusion of varied demographic groups, clinical conditions, and MR field strength addresses potential confounders.

The subjects upon whom the device was trained and tested include healthy subjects, mild cognitive impairment patients, Alzheimer's disease patients, and small vessel disease patients from young adults to elderly. The multicenter study was adapted to collect scans from various vendors including Philips, Siemens Healthineers, and GE Healthcare and MR scans using general clinical protocols were collected.

For the 3D T1 weighted images, a total of 72 3D T1 weighted scan cases were used for accuracy, and 72 cases were used for reproducibility. The test dataset included MR images from Philips (54 subjects), Siemens Healthineers (53 subjects), and GE (37 subjects) scanners, using both 1.5T and 3.0T field strengths. Subjects were collected from multiple countries, including the United States, the United Kingdom, China, and Germany, with ages ranging from young adults to the elderly (20s to 90s).

As a result, the segmentation accuracy compared to expert manual segmentations of 3D T1 MRI scans was evaluated using Dice's coefficient metric. For major subcortical brain structures Dice's coefficients were above 80% and for major cortical were above 75%.

Brain structural reproducibility of repeated 3D T1 MRI scans for same subjects was evaluated by using the percentage absolute volume differences. The mean percentage absolute volume differences for all major subcortical and cortical structures were 5% or less.

For the T2 weighted FLAIR images, the accuracy test dataset comprised 160 T2 weighted FLAIR scan

cases, and the reproducibility test dataset comprised 85 cases. The sample size supports robust performance validation. The test dataset included MR images from Philips (92 subjects), Siemens Healthineers (65 subjects), and GE (88 subjects) scanners, using both 1.5T and 3.0T field strengths. Subjects were collected from multiple countries, including the United States, Brazil and Republic of Korea with ages ranging from young adults to the elderly (20s to 90s).

SwiftSight-Brain performance was then evaluated by comparing segmentation accuracy with expert manual segmentations and by measuring segmentation reproducibility between same subject scans. The system yields reproducible results that are well correlated with expert manual segmentation.

SwiftSight-Brain's lesion segmentation accuracy compared to expert manual segmentations of T2 weighted FLAIR scan was evaluated using Dice's coefficient metric, which exceeds 0.80. The brain lesion segmentation reproducibility was evaluated using repeated T2 weighted FLAIR scan pairs of subjects with brain lesions. The mean absolute lesion volume difference was less than 0.25cc.

9. Conclusion

The subject device is substantially equivalent in the areas of technical characteristics, general function, application, and indications for use. The new device does not introduce fundamentally new scientific technology, and the device has been validated through the system level test. Therefore, we conclude that the subject device described in this submission is substantially equivalent to the predicate device (K242215, Neurophet AQUA V3.1).