AIRS Medical Inc.
℅ Jihyeon Seo
RA Manager
8-9F, CS Tower, 1838, Nambusunhwan-ro, Gwanak-gu
Seoul, Seoul 08788
SOUTH KOREA

October 14, 2021

Re: K210999
Trade/Device Name: SwiftMR
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: August 31, 2021
Received: September 2, 2021

Dear Jihyeon Seo:

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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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)*
K210999

Device Name
SwiftMR

Indications for Use *(Describe)*
SwiftMR is a stand-alone software solution intended to be used for acceptance, enhancement and transfer of brain MRI images in DICOM format. It can be used for noise reduction and increasing image sharpness for non-contrast enhanced MRI images.
SwiftMR is not intended for use on mobile devices.

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.

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AIRS MEDICAL

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.

I. SUBMITTER

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Date Prepared: March 29, 2021

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: LLZ

III. PREDICATE DEVICE

Primary Predicate Device: SubtleMR – K191688 by Subtle 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 standard of care MRI images in DICOM format. The deep learning algorithm produces enhanced images as outputs with reduced noise and increased sharpness in DICOM format. The device applies both denoising and sharpness increase functions simultaneously.

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:

- Upload MR images that have been taken or converted to the DICOM format
- Image quality enhancement using Deep Learning model
- Download enhanced MR image as DICOM format

There are two deep learning algorithms that should be selected by users according to the pulse sequences. One is for the general pulse sequences and the other is for the TOF pulse sequences. The two deep learning algorithms share the same network architecture, input data generation method, training procedures. The only difference between the two deep learning algorithms is the input / label dataset used for training.

510(k) Summary

After integration with the facilities PACS, SwiftMR performs image processing in the background automatically. At the same time, SwiftMR allows logged-in users to use its functions and change product settings through the client application. When logged in as the System Admin, the function is available to the 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.

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 and saves the images in PACS 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 back to PACS.

If the user wishes to monitor this automated workflow to check on the status of image processing, he/she can log in to the Client App, and notifications will be received upon each task completion. Detailed information is also available when the main worklist is opened, and MR Study and/or Series in concern is selected.

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

V. INDICATIONS FOR USE

SwiftMR is a stand-alone software solution intended to be used for acceptance, enhancement and transfer of brain MRI images in DICOM format. It can be used for noise reduction and increasing image sharpness for non-contrast enhanced MRI images.

SwiftMR is not intended for use on mobile devices.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

The subject device and predicate are both software applications that are loaded into PACS. Both systems have been developed for image enhancement on DICOM images generated by an MRI. 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	Predicate Device (K191688)	Subject Device (SwiftMR)	Differences
Physical Characteristics	Software device that operates on off-the-shelf computer hardware	Same as predicate	No Difference
Computer	Linux Compatible	PC Compatible	Differences are basically in the computer operating system but also may have some differences in the processor speeds, amount of RAM memory, monitors, and hard drive space requirements. However, the subject device and the predicate device are substantially equivalent

			in the areas of technical characteristics, general function, application, and intended use and the computer platform differences do not raise any new potential safety risks. Therefore, it is our determination that there is “No impact on safety or efficacy” and there are no new potential or increased safety risks.
DICOM Standard Compliance	The software processes DICOM compliant image data	Same as predicate	No Difference
Modalities	MRI	Same as predicate	No Difference
Image Enhancement Algorithm Description	The predicate software implements an image enhancement algorithm using convolutional neural network-based filtering. Original images are enhanced by running through a cascade of filter banks, where thresholding and scaling operations are applied. Separate neural network-based filters are obtained for noise reduction and sharpness increase. The parameters of the filters were obtained through an image guided optimization process.	SwiftMR implements an image enhancement algorithm using convolutional neural network-based filtering. Original images are enhanced by running through a cascade of filter banks, where thresholding and scaling operations are applied. Neural network-based filters that simultaneously perform noise reduction and sharpness increase functions are obtained. The parameters of the filters were obtained through an image guided optimization process.	The only difference is in how the neural network-based filter exists. As for the predicate device, there are separate filters for noise reduction and sharpness increase. On the other hand, there are neural network-based filters that simultaneously perform both functions for the subject device. However, the same functions, which are noise reduction and sharpness increase, are applied by the filters. Therefore, the difference does not raise new questions of safety or effectiveness.
Workflow	The predicate software operates on DICOM files on the file system, enhances the images, and stores the enhanced images on the file system. The receipt of original DICOM image files and delivery of enhanced images as DICOM files depends on other software systems. Enhanced images co-exist with the original images.	Same as predicate	No Difference

510(k) Summary

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, Integration/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 compared to the value of the original image series. 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% or more after applying SwiftMR for at least 90% of the test datasets. This test passed.

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

VIII. 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.