Apollo Medical Imaging Technology Pty. Ltd.
% Prithul Bom
Official Correspondent
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

December 31, 2019

Re: K192912
Trade/Device Name: AutoMIStar
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: December 17, 2019
Received: December 18, 2019

Dear Prithul Bom:

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 Mills, PhD
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K192912

Device Name

AutoMIStar

Indications for Use *(Describe)*

AutoMIStar is a medical image post-processing software package to be used by trained professionals, including but not limited to physicians and medical technicians. The software runs on a standard "off-the-shelf" computer or a virtual platform with Windows operating system, and can be used to perform image viewing, processing and analysis of brain images acquired by DICOM compliant imaging devices.

AutoMIStar provides general viewing of DICOM images, with analysis capabilities for functional imaging data including a CT Perfusion Module and a DWI (diffusion-weighted MRI) Module.

The CT Perfusion Module is used for visualization and analysis of contrast enhanced CT Perfusion (CTP) dataset, showing properties of changes in contrast over time. This function includes calculation of various parameters related to tissue flow (perfusion) and tissue blood volume.

The DWl Module is used to visualize local water diffusion properties from the analysis of diffusion-weighted MRI 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.

510(k) Summary

Applicant:	Apollo Medical Imaging Technology Pty. Ltd. Suite 611, 365 Little Collins Street Melbourne, Vic 3000, Australia	
Contact Person:	Qing Yang, PhD Director Phone: 61-3-9995 6190	
Date Prepared:	November 27, 2019	
Device Trade Name:	AutoMIStar	
Common Name:	PACS - Picture Archiving Communications System	
Classification:	**Regulation Number:**	21 C.F.R.§892.2050
	Classification Panel:	Radiology
	Device Class:	Class II
	Product Code:	LLZ
Predicate Devices:	IschemaView RAPID (K121447)	

Device Description:

AutoMIStar is a software package that provides visualization and processing of medical imagesacquired by CT (Computed Tomography) and MRI (Magnetic Resonance Imaging) scanners, as an aid to physician diagnosis. It can be installed and run on a PC, laptop or virtual machine running a Microsoft Windows operating system. It provides viewing, quantification, analysis and reporting capabilities.

AutoMIStar also provides processing and analysis of functional and dynamic imaging datasets including CT Perfusion (CTP) and diffusion-weighted MRI (DWI). It provides tools to perform the following type of advanced analysis:

- time intensity plots for dynamic time courses;
- volumetry of threshold maps;
- calculation of mismatch between volumes of different threshold maps;

AutoMIStar can be configured to connect to various DICOM devices (modality scanners, workstations, PACS) via the hospital medical imaging network to receive CT or MRI images as they become available. It supports transfer of DICOM images using the DICOM standard network protocol, and allows import of DICOM images from storage media. It provides automated workflow to processes received data and sends post-processed results to designated DICOM devices.

It can also be configured to send post-processed results to designated recipients via email through the hospital email system.

Intended Use /Indications for Use:

AutoMIStar is a medical image post-processing software package to be used by trained professionals, including but not limited to physicians and medical technicians. The software runs on a standard “off-the-shelf” computer or a virtual platform with Windows operating system, and can be used to perform image viewing, processing and analysis of brain images acquired by DICOM compliant imaging devices.

AutoMIStar provides general viewing of DICOM images, with analysis capabilities for functional imaging data including a CT Perfusion Module and a DWI (diffusion-weighted MRI) Module.

The CT Perfusion Module is used for visualization and analysis of contrast enhanced CT Perfusion (CTP) dataset, showing properties of changes in contrast over time. This function includes calculation of various parameters related to tissue flow (perfusion) and tissue blood volume.

The DWl Module is used to visualize local water diffusion properties from the analysis of diffusion-weighted MRI data.

Technical Characteristics:

AutoMIStar provides the following functions:

- receive DICOM images from various DICOM devices (CT/MRI scanners, PACS and Workstations) and send DICOM images to designated DICOM devices;
- process DICOM images received from multiple sources to provide visualization of changes of tissue perfusion and diffusion;
- send processed results as DICOM images to designated DICOM devices;
- send summary results to designated recipients via customer approved email server using the SMTP protocol with security extensions to provide secure emailing.

AutoMIStar is a DICOM-compliant PACS softwarethat provides functionality to transfer, process, and display of CT and MR imaging data including dynamically acquired CT perfusion imaging data and diffusion-weighted MRI (DWI).

AutoMIStar runs on a standard "off-the-shelf' computer with Windows operating system, and can seamlessly integrate into an existing radiological data network. AutoMIStar is entirely independent from CT, MRI, or PACS platforms.

The primary users of AutoMIStar software are medical imaging professionals who view and analyse CT and MRI images. The results generated by AutoMIStar provideadditional diagnostic information, which is derived from the temporal/diffusion features of the nativeCT or MRI images.

Substantial Equivalence:

In comparison with RAPID, AutoMIStar has the same intended use and similar indications, technological characteristics and principles of operation as its predicate device as described in the comparison table below.

Device	**AutoMIStar**	**IschemaView's RAPID**
Product Code	**LLZ**	**LLZ**
Regulation	**21 CFR §892.2050**	**21 CFR §892.2050**
Intended Use / Indications for Use	AutoMIStar is a medical image post-processing software package to be used by trained professionals, including but not limited to physicians and medical technicians. The software runs on a standard "off-the-shelf" computer or a virtual platform with Windows operating system, and can be used to perform image viewing, processing and analysis of brain images acquired by DICOM compliant imaging devices. AutoMIStar provides general viewing of DICOM images, with analysis capabilities for functional imaging data including a CT Perfusion Module and a DWI (diffusion-weighted MRI) Module. The CT Perfusion Module is used for visualization and analysis of contrast enhanced CT Perfusion (CTP) dataset, showing properties of changes in contrast over time. This function includes calculation of various parameters related to tissue flow (perfusion) and tissue blood volume. The DWl Module is used to visualize local water diffusion properties from the analysis of diffusion-weighted MRI data.	iSchemaView's RAPID is an image processing software package to be used by trained professionals, including but not limited to physicians and medical technicians. The software runs on a standard "off-the-shelf" computer or a virtual platform, such as VMware, and can be used to perform image viewing, processing and analysis of brain images. Data and images are acquired through DICOM compliant imaging devices. iSchemaView's RAPID provides both viewing and analysis capabilities for functional and dynamic imaging datasets acquired with CT Perfusion and MRI including a Diffusion Weighted MRI (DWl) Module and a Dynamic Analysis Module (dynamic contrast enhanced imaging data for MRI and CT). The DWl Module is used to visualize local water diffusion properties from the analysis of diffusion weighted MRI data. The Dynamic Analysis Module is used for visualization and analysis of dynamic imaging data, showing properties of changes in contrast over time. This functionality includes calculation of parameters related to tissue flow (perfusion) and tissue blood volume.
PACS Functionality		
Basic PACS Functions	View, process and analyze medical images. Performs standard PACS functions with	Same

	respect to querying and listing.	
Computer Platform	Standard off-the-shelf PC workstation	Same
	Virtual platform such as VMware	Same
DICOM Compliance	Yes	Yes
Functional Overview	AutoMIStar is a software package that provides for thevisualization and study of changes of tissue in digitalimages captured by CT and MRI. AutoMIStar providesviewing and quantification.	Same
Data Acquisition	Receives medical image data from DICOM compliant imaging devices and modalities	Same
Data/Image Types	Computed Tomography (CT)	Same
	Magnetic Image Resonance (MRI)	Same
Acquisition and Modalities Features		
CT	CT Perfusion (CTP)	Yes
MRI	Diffusion Weighted Image (DWI)	Yes
Computed Parameter Maps		
CT Perfusion	Cerebral blood flow (CBF)	Yes
	Cerebral blood volume (CBV)	Yes
	Mean transit time (MTT)	Yes
	Delay time (DT)	Tmax
Diffusion MRI	Isotropic DWI (isoDWI)	Yes
	Apparent diffusion coefficient (ADC)	Yes
	Exponential ADC (eADC)	Yes
Measurement Tools		
CT and MRI Tools	Arterial input function (AIF) Venous output function (VOF)	Yes
	Time-course	Yes
	Brain mask	Yes
	Region of interest (ROI) and Volumetry	Yes
	Volumetric comparison between 2 ROIs	Yes
	Motion correction	Yes
	Export parameter maps PACS and DICOM file systems	Yes
	Acquire, transmit, process, and store medical images	Yes

Difference in Indications for Use with Respect to the Predicate Device:

AutoMIStar does not include the functionality, and is therefore not indicated for processing or analyzing images acquired through dynamic contrast enhanced Magnetic Resonance Imaging (MRI) protocols. However, AutoMIStar is indicated for the same functionality as the predicate device with respect to CTP or DWI datasets. Such minor differences indications do not alter the intended diagnostic use of the device and do not affect its safety and effectiveness with respect to CTP and DWI functionalities.

Difference in Technical Performance with Respect to the Predicate Device:

With regards to CT Perfusion analysis, AutoMIStar provides a Delay Time (DT) parameter derived from an improved deconvolution method with delay- and dispersion-correction. While Tmax is derived using a deconvolution method without delay- and dispersion-correction, both DT and Tmax are similar timing parameters related to the same arterial delay effects of blood circulation.

Performance Data:

AutoMIStar complies with DICOM (Digital Imaging and Communications in Medicine), developed by the American College of Radiology and the National Electrical Manufacturers Association. NEMA PS 3.1-3.20.

Apollo performed software verification and validation testing of the device and additional performance testing using published perfusion phantom and diffusion phantom data, which include a wide range of clinically relevant values of perfusion and diffusion parameters respectively as ground truth. Regression analysis between the output of the AutoMIStar device and the ground truth values were performed, and also compared to published results between the ground truth values and the outputs of seven other commercially available and academic CTP software packages. The results of performance testing showed that the AutoMIStar device achieved the pre-established performance goals for all perfusion and diffusion parameters including cerebral blood flow (CBF), cerebral blood volume (CBV), mean transit time (MTT), delay time (DT) and apparent diffusion coefficient (ADC).

Performance validation was also conducted on key device outputs including perfusion and diffusion threshold maps and volumes demonstrating substantial equivalence. Together with software verification and validation, the performance validation demonstrated that AutoMIStar satisfies all design requirements and device specifications.

Conclusions:

AutoMIStar is substantially equivalent to the predicate device RAPID in terms of indications for use, technological characteristics, principles of operation, and safety and/or effectiveness.

Additionally, substantial equivalence was demonstrated via performance validation testing and software verification and validation testing of the AutoMIStar system. The performance validation testing demonstrated that AutoMIStar provides accurate representation of key perfusion and diffusion parameters associated with the intended use of the software. Software verification and validation testing demonstrated that AutoMIStar met all design requirements and specifications. Thus, the AutoMIStar device is substantially equivalent, and at least as safe and effective as the predicate device.