March 1, 2023

Advantis Medical Imaging Single Member P.C.
% Paris Ziogkas
CEO
Eleftheriou Venizelou Avenue 99
Nea Smirni, Athens, 17123
GREECE

Re: K222975
Trade/Device Name: Advantis Platform
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: January 26, 2023
Received: January 30, 2023

Dear Paris Ziogkas:

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,

Daniel M. Krainak, Ph.D.
Assistant Director
Magnetic Resonance and Nuclear Medicine Team
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222975

Device Name
Advantis Platform

Indications for Use *(Describe)*
Advantis Platform provides analysis and visualization capabilities of dynamic MRI data of the brain and prostate, presenting the derived properties and parameters in a clinically useful context.

Advantis Platform is intended as a general medical image management and processing system. Advantis Platform is intended to be used by trained healthcare professionals and provides information that, in a clinical setting, may assist in the interpretation of brain and prostate MR studies of adult population.

Diagnosis should not be made solely based on the analysis performed using Advantis Platform.

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

K222975

Submitter

Submitter Name : Advantis Medical Imaging Single Member P.C.

Submitter Address: Eleftheriou Venizelou Avenue 99, Nea Smirni, Athens, Greece, 17123

Phone : +302109329558

Contact Person : Paris Ziogkas (pz@advantis.io)

Date prepared : January 26th, 2023

Device

Device Trade Name : Advantis Platform

Device Common Name : PACS

Device : System, Image Processing, Radiological

Classification Name : Medical image management and processing system

Classification Regulation: 21 CFR 892.2050

Class : II

Panel : Radiology

Product Code : LLZ

Predicate Device

Primary Predicate 1 : K202808, Brainance MD, manufactured by Advantis Medical Imaging Single Member P.C.

Primary Predicate 2 : K180336, syngo.MR Applications, manufactured by Siemens Medical Solutions USA, Inc.

Reference Device Name : K092954, CADstream Version 5, manufactured by Merge CAD Inc

Device Description

Advantis Platform is a web-accessible medical viewing and post-processing software application.

Advantis Platform offers comprehensive functionality for dynamic image analysis and visualization of brain and prostate MRI data which are acquired through DICOM-compliant imaging devices and modalities.

The main functionalities of Advantis Platform are listed below.

Brain MRI-related functionalities include:

- BOLD: BOLD fMRI analysis is used to highlight small magnetic susceptibility changes in the human brain in areas with altered blood flow resulting from neuronal activity.
- DTI: Diffusion analysis is used to visualize local water diffusion properties from the analysis of diffusion-weighted MRI data. Fiber tracking utilizes the directional dependency of the diffusion to display the white matter structure in the brain.
- DSC Perfusion: Calculations of perfusion-related parameters that provide information about the blood vessel structure and characteristics as a response of the brain to a specific contrast agent.

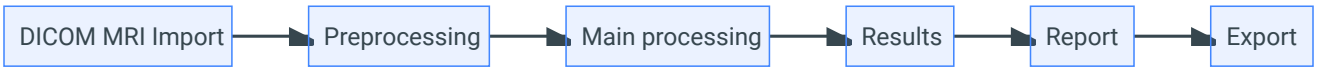
Prostate MRI-related functionalities include:

- Diffusion-Weighted Imaging (DWI) processing: Diffusion analysis is used to visualize local water diffusion properties from the analysis of diffusion-weighted MRI data.
- Dynamic Contrast-Enhanced Perfusion (DCE Perfusion) processing: Calculations of perfusion-related parameters that provide information about the tissue response to the injection of a contrast medium.

Advantis Platform, apart from the image processing and manipulation functions, provides a wide range of visualization tools, data handling, and reporting features.

- Image uploading, storing, and exporting
- Data handling
- Image viewing
- Reporting feature

The flowchart below illustrates the overall architecture of Advantis Platform.



Intended use

Advantis Platform is a web-accessible medical viewing and post-processing software application, with a specific focus on providing algorithms designed to analyze brain and prostate MRI data. The device is web-accessible and can be used with data and images acquired through DICOM-compliant imaging devices and modalities from adult population.

Intended users

The device is intended to be used by medical personnel, including but not limited to radiologists and medical technicians, trained in the methods provided by the application.

Environment of Use

Advantis Platform is intended to be used in healthcare organizations including but not limited to hospitals, imaging centers, and remote locations by healthcare professionals (e.g. teleradiology companies) with authorization and granted access to patient images, demographic, and report information.

Indications for Use

Advantis Platform provides analysis and visualization capabilities of dynamic MRI data of the brain and prostate, presenting the derived properties and parameters in a clinically useful context.

Advantis Platform is intended as a general medical image management and processing system. Advantis Platform is intended to be used by trained healthcare professionals and provides information that, in a clinical setting, may assist in the interpretation of brain and prostate MR studies of adult population.

Diagnosis should not be made solely based on the analysis performed using Advantis Platform.

Comparison of Technological Characteristics with the Predicate Device

Advantis Platform is the multi-organ post-acquisition image processing software provided by Advantis Medical Imaging Single Member P.C. Advantis Platform consists of two key modules, the Brain and the Prostate module.

The two modules are based on the same medical device system and share some common characteristics. Nevertheless, they are distinct from each other.

It has to be noted that the Brain module of Advantis Platform refers to the already FDA cleared medical device software Brainance MD (K202808).

More specifically, the Brain module and Brainance MD are identical with the only differences being their trade names and the fact that Brain is considered a module within the device Advantis Platform.

The Prostate is the latest module that the manufacturer has developed and included in Advantis Platform.

With this premarket submission, the new prostate module is introduced to extend the Advantis Platform workflow. Brainance MD on the other hand is now considered a module (Brain module) under the Advantis Platform software.

	Subject Device	Primary Predicate Device 1	Primary Predicate Device 2	Reference Device	Differences
Device Name	Advantis Platform	Brainance MD	syngo.MR Applications	CADstream Version 5	-
510(k)Number	K222975	K202808	K180336	K092954	-
Manufacturer	Advantis Medical Imaging Single Member P.C.	Advantis Medical Imaging Single Member P.C	Siemens Medical Solutions USA, Inc.	Merge CAD Inc	-
Product Code	LLZ	LLZ	LLZ	LLZ	-
Class	II	II	II	II	-
Operating Environment	Client-server	Client-server	Client-server, "Off-the-shelf" windows PC workstation	"Off-the-shelf" windows PC workstation	Note 1
Input data	DICOM compliant MR data, Nifti	DICOM compliant MR data, Nifti	DICOM compliant MR data, Nifti	DICOM compliant MR data	Note 2
Organ/Area	Brain, Prostate	Brain	general MRI studies including Prostate	general MRI studies including Prostate	Note 3
General Functionality	2D MPR visualization, 3D Visualization, Volumes of interest, Measurement tools, DICOM	ditto	ditto	ditto	-

	Subject Device	Primary Predicate Device 1	Primary Predicate Device 2	Reference Device	Differences
	compliant node, Reporting tool				
Dynamic Analyses	Brain module:BOLD, DTI, DSC Perfusion Prostate module: DWI,DCE	Brain module:BOLD, DTI, DSC Perfusion	Prostate module: DWI,DCE	Prostate module: DWI,DCE	Note 4
Environment of Use	Intended for use in clinical/hospital environment	ditto	ditto	ditto	-

Notes

Note 1

The subject device and the two predicate devices make use of the client server model while the reference device operates on “Off-the-shelf” windows PC workstations. The aforementioned minor difference does not raise any safety or performance issues, as in all four devices, the user is presented with a graphical user interface that allows them to import exams, process and display them in two and three dimensions and finally store them. Even though one of the reference devices operates only on “Off-the-shelf” workstation from the user’s perspective all devices are functionally equivalent. The aforementioned difference does not raise any safety or performance issues.

Note 2

The subject device and predicate devices can accept and proccess input data of both DICOM and Nifti format while the reference device can only accept and process DICOM data. The aforementioned difference does not raise any safety or performance issues.

Note 3

Advantis Platform is intended to be used for the processing of brain and prostate MRIs. In regards to the Brain characteristics the device is equivalent to the Primary Predicate Device 1. More specifically it is actually the same product but with a different trade name. With reference to the Prostate characteristics the device is equivalent to the Primary Predicate Device 2. The Primary Predicate Device 2 is compatible with MR images

from any anatomical site, amongst which prostate MR images. Advantis Platform is intended to be used with MR images including but not limited to prostate MRIs. As the intended use of Advantis Platform is overlapping with the intended use of the Primary Predicate Device 2 it is concluded that this difference does not raise any questions on the performance and safety of Advantis Platform compared to Primary Predicate Device 2.

Note 4

All of the brain related modalities processed by Advantis Platform, are also processed by the Primary Predicate Device 1 because they practically refer to the same device, having essentially identical principles of operation. Concerning the prostate related modalities Advantis Platform and the Primary Predicate Device 2 have essentially identical principles of operation.

Software

Advantis Platform was successfully validated and verified against the requirements specification and its intended use. The results from the validation and verification activities justify that Advantis Platform meets the product requirement specifications and intended use, which is deemed to be substantially equivalent to the predicate devices.

Validation and verification activities were conducted in a controlled environment and in compliance with IEC 62304, ISO 13485:2016 and 21 CFR 820. Advantis Platform is also in compliance with the DICOM standard.

The verification and validation activities conducted demonstrate that Advantis Platform is at least as safe and effective as the predicate devices and does not introduce any new risks.

Performance

The performance testing conducted demonstrates that Advantis Platform is as safe and as effective to use as the predicate devices and does not introduce any new risks.

More specifically, apart from the standard software verification and validation testing conducted and documented in compliance with the FDA Guidance, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices” and “Technical Performance Assessment of Quantitative Imaging in Radiological Device Premarket Submissions”, a detailed comparative study was performed between the subject device, the predicate and reference devices on the basis of the core functionalities.

Performance Testing Summary

Concerning the Brain module of Advantis Platform no performance testing was performed due to the fact that the Brain module and the Primary Predicate Device 1 are actually the same product with different trade names. No change was made on the brain related functions.

Concerning the Prostate module, a comparative study was conducted in order to validate the equivalency between the results computed by Advantis Platform and the ones computed the Primary predicate device 2 and the Reference device.

The maps that resulted from the processing were compared using ICC & Bland-Altman analysis on all valid pixel values for every subject in the dataset. The Weighted Cohen's Kappa statistic and its 95% confidence intervals (CIs) were used to assess interobserver agreement of maps consisting of categorical ordinal data.

The final results matched the criteria of acceptance/approval priorly set by the manufacturer and thus equivalency among the devices on a result level was proven.

Discussion Summary

According to the comparisons among the subject device, the predicate and reference devices, we can conclude that the subject device does not raise any new potential safety risks when compared to the chosen predicate and reference devices and performs in accordance with its intended use.

The subject device is substantially equivalent to the predicate devices. Substantial equivalence is based on the following observations:

- The indications for use and intended uses of the subject device and predicate devices are equivalent
- The subject and predicate devices consist of software applications which visualize and analyze MR data
- The subject and predicate devices are standalone software applications to facilitate the import and visualization of MR data sets
- The subject and predicate devices offer similar visualization and processing functionalities and incorporate well known and extensivelly tested methodologies
- The subject and predicate devices are intended to be used in the same environment and by trained healthcare professionals
- Performance testing demonstrates that the subject device performs at least as safely and effectively as the predicate devices

Conclusion

Based on the information submitted in this premarket notification, and based on the indications for use, technological characteristics, performance testing and technological comparison to the predicate devices, Advantis Platform raises no new risks of safety and effectiveness and is substantially equivalent to the predicate devices.

Last update: 2023-01-30