Medilab Manutencao E Sitemas Ltda
Jorge Millan
Regulatory Consultant
Rua Amaral, 80, Andarai
Rio De Janeiro, Rio De Janeiro 20541-155
Brazil

June 23, 2023

Re: K223048
Trade/Device Name: Medisystem Pacs
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: May 22, 2023
Received: May 23, 2023

Dear Jorge Millan:

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 and Part 809); 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,

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software Team
DHT8B: Division of Radiological Imaging Devices and Electronic Products
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)*
K223048

Device Name
MediSystem PACS

Indications for Use *(Describe)*

MediSystem PACS is intended for use as a diagnostic and analysis tool for diagnostic images for hospitals, imaging centers, radiologists, reading practices and any user who requires and is granted access to patient image, demographic and report information. MediSystem PACS displays and manages diagnostic quality DICOM images. MediSystem PACS is not intended for diagnostic use with mammography images. Usage for mammography is for reference and referral only. MediSystem PACS is not intended for diagnostic use on mobile devices.

Contraindications: MediSystem PACS is not intended for the acquisition of mammographic image data and is meant to be used by qualified medical personnel.

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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MEDILAB MANUTENCAO E SISTEMAS LTDA

MediSystem PACS 510K Summary – June 21, 2023

510(K) Summary

Submitter Information

Submitter	MEDILAB MANUTENCAO E SISTEMAS LTDA RUA AMARAL, 80, ANDARAI Rio de Janeiro, Brazil 20541-155
Contact:	Jorge Millan, PhD
Telephone number	(786) 416-5587
E-mail	jmillan@sigmabiomedical.com
Date prepared:	June 21, 2023

Subject Device Name

Trade/Proprietary Name:	MediSystem PACS
Regulation Number:	892.2050
Regulation Name:	Medical Image management and processing system
Product Code:	LLZ
Class	II
Panel	Radiology

Predicate Device

Predicate Device:	MediLab
Sponsor	SIGMA SCIENTIFIC SERVICES LLC
510(K)	K221065
Regulation Number:	892.2050
Regulation Name:	Medical Image management and processing system
Product Code:	LLZ
Class	II
Panel	Radiology

Device Description:

The MediSystem PACS is a Web-based DICOM medical image viewer that allows downloading, reviewing, manipulating, visualizing and printing medical multi-modality image data in DICOM format, from a client machine. MediSystem PACS is a server-based solution that connects to any PACS and displays DICOM images within the hospital, securely from remote locations, or as an integrated part of an EHR or portal. MediSystem PACS enables health professionals to access, manipulate, measure DICOM images and collaborate real-time over full quality medical images using any web-browser without installing client software. Supported Web browsers are: Microsoft Edge 79 or later, Mozilla Firefox 58 or later, Google Chrome 63 or later.

Indications for Use:

MediSystem PACS is intended for use as a diagnostic and analysis tool for diagnostic images for hospitals, imaging centers, radiologists, reading practices and any user who requires and is granted access to patient image, demographic and report information. MediSystem PACS displays and manages diagnostic quality DICOM images. MediSystem PACS is not intended for diagnostic use with mammography images. Usage for mammography is for reference and referral only. MediSystem PACS is not intended for diagnostic use on mobile devices.

Contraindications: MediSystem PACS is not intended for the acquisition of mammographic image data and is meant to be used by qualified medical personnel.

Non-Clinical Data:

Non-clinical product evaluation to demonstrate safety and effectiveness was conducted. Non-clinical testing includes:

Software Verification and Validation
Software verification and validation testing were conducted on the MediSystem PACS and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern, since a failure or latent

flaw in the software would lead to a delayed delivery of appropriate medical care. Documentation includes level of concern, software requirements and specifications, design architecture, risk analysis and software validation and verification.

Performance Testing (Measurement Accuracy) was conducted on the MediSystem PACS to determine measurement accuracy when performing the various distance, area and angle measurements.

Predicate Devices

MediSystem PACS is equivalent to MediLab by SIGMA SCIENTIFIC SERVICES LLC cleared under K221065.

Comparison with the Predicate Devices [21 CFR 807.92(a) (6)]: MediSystem PACS is comparable with and substantially equivalent to MediLab System.

Technical Characteristics Comparison:

The basic and main technical features of the subject device are the same as the predicated device

Feature Comparison:

Subject device has similar features and functionality as the predicate device:

Product comparison

Feature	MEDILAB	MEDISYSTEM PACS
K#	K221065	
Intended Use	MediLab software is intended for use as a diagnostic and analysis tool for diagnostic images for hospitals, imaging centers, radiologists, reading practices and any user who requires and is granted access to patient image, demographic and report information. MediLab displays and manages diagnostic quality DICOM images. Medilab is not intended for diagnostic use with mammography images. Usage for mammography is	MediSystem PACS software is intended for use as a diagnostic and analysis tool for diagnostic images for hospitals, imaging centers, radiologists, reading practices and any user who requires and is granted access to patient image, demographic and report information. MediSystem PACS displays and manages diagnostic quality DICOM images. MediSystem PACS is not intended for diagnostic use with

	for reference and referral only. MediLab is not intended for diagnostic use on mobile devices. Contraindications: MediLab is not intended for the acquisition of mammographic image data and is meant to be used by qualified medical personnel.	mammography images. Usage for mammography is for reference and referral only. MediSystem PACS is not intended for diagnostic use on mobile devices. Contraindications: MediSystem PACS is not intended for the acquisition of mammographic image data and is meant to be used by qualified medical personnel.
Mammographic use	No	No
DICOM image loading and visualization	Yes	Yes
Patient study search data	Yes	Yes
User authentication	Yes	Yes
Window level	Yes	Yes
Rotate/pan/zoom/fit to screen	Yes	Yes
Image display operations	Flip horizontal, vertical Rotate left, right Clear transform Magnification Scroll Layout 1x1 –3x3 Thumbnails left, right, top, bottom PET Fusion Volumetric rendering	Flip horizontal, vertical Rotate left, right Clear transform Magnification Scroll Layout 1x1 –3x3 Thumbnails left, right, top, bottom PET Fusion Volumetric rendering
Measurement functions	Line, angle, area	Line, angle, area
Measurement accuracy	1% for distance 2% for angle and distance	1% for distance 2% for angle and distance
Annotations	Text	Text
Report Generation	Yes	Yes
Print reports	PDF	PDF
Export	Yes	Yes
Export reports to CD	No	Yes
Share function	Yes	Yes
DICOM Windowing	Yes	Yes
Low Pass Filter	No	No
Imaging modalities	US, CT, MRI, XRay	US, CT, MRI, XRay
Communications	DICOM	DICOM

Operating System for Diagnostic Viewing	Windows, Linux, Mac	Windows, Linux, Mac
Browser supported	Edge, Firefox, Chrome	Edge, Firefox, Chrome
Mobile Device Support for Viewing	No	No
Transfer/Storage/Display of Medical images	Yes	Yes
Network access	Connects to existing PACS	Connects to existing PACS

Evaluation of similarities and differences:

- MediSystem PACS and MediLab have similar intended use, functionality and similar Web technologies. In terms of use and functions both systems access, upload and display DICOM images and metadata and provide tools and resources to the physician for study review and analysis. Both systems are hosted in Web servers and are equipped with security features and user authentication.
- There are no differences between both systems.

Conclusion:

The subject device has similar technology characteristics and has similar intended use and functionality as the predicate device. Product testing included software validation and verification and performance testing such as distance, area and angle measurement accuracy. These tests show similar and equivalent performance. Thus, there are no differences between the devices that affect the usage, safety and effectiveness, thus no new question is raised regarding the safety and effectiveness. The non-clinical performance test data and software verification and validation demonstrate that the MediSystem PACS performs comparably to and it is as safe and effective as the predicate device. In accordance with the 21 CFR Part 807 and based on the information provided in this premarket notification, MediSystem PACS is substantially equivalent to the predicate that is currently marketed for the same intended use.