Sigma Scientific Services LLC
Jorge Millan
Biomedical Director
7737 N University Drive, Suite 101
Tamarac, Florida 33321

June 10, 2022

Re: K221065
Trade/Device Name: MediLab
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: April 5, 2022
Received: April 12, 2022

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)*
k221065

Device Name
MediLab

Indications for Use *(Describe)*

MediLab 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 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.

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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510(K) Summary

Submitter Information

Submitter	SIGMA SCIENTIFIC SERVICES LLC 7737 N UNIVERSITY DRIVE, SUITE 101 TAMARAC, FL 33321
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E-mail	sigmabiomedical@gmail.com
Date prepared:	June 6, 2022

Subject Device Name

Trade/Proprietary Name:	MediLab
Regulation Number:	892.2050
Regulation Name:	Medical image management and image processing System
Product Code:	LLZ
Class	II
Panel	Radiology

Predicate Device

Predicate Device:	ZeeroMED View
Sponsor	O3 ENTERPRISE SRL
510(K)	K200546
Regulation Number:	892.2050
Regulation Name:	Medical image management and image processing System
Product Code:	LLZ
Class	II
Panel	Radiology

Reference Predicates

Reference Devices:	IMPLANTER DENTAL PLANNING SOFTWARE, K173083 aPROMISE X, K220590
Regulation Number:	892.2050
Regulation Name:	Medical image management and image processing System
Product Code:	LLZ
Class	II
Panel	Radiology

Device Description:

The MediLab is a DICOM medical image viewer that allows downloading, reviewing, manipulating, visualizing and printing medical multi-modality image data in DICOM format, from a client machine. MediLab 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. MediLab 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.

Indications for Use:

MediLab 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 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.

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 MediLab system 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 MediLab system to determine measurement accuracy when performing the various distance and area measurements.

Predicate Devices

Comparison with the Predicate Devices [21 CFR 807.92(a) (6)]: MediLab is comparable with and substantially equivalent to ZeeroMED View by O3 ENTERPRISE cleared under K200546. Medilab is also comparable to the reference devices cleared under K173083 and K220590.

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 and reference devices:

Product comparison to primary predicate

Feature	ZeeroMED View	MEDILAB	Comparison to Predicate
K#	K200546	K221065	N/A
Intended Use	ZeeroMED View 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. ZeeroMED View displays and manages diagnostic quality DICOM images. ZeeroMED View is not intended for diagnostic use with mammography images. Usage for mammography is for reference and referral only. ZeeroMED View is not intended for diagnostic use on mobile devices. Contraindications: The ZeeroMED View is not intended for the acquisition of mammographic image data and is meant to be used by qualified medical personnel.	The 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 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.	Similar
Mammographic use	No	No	No difference
DICOM image loading and visualization	Yes	Yes	No difference
Patient study search data	Yes	Yes	No difference
User authentication	Yes	Yes	No difference
Window level	Yes	Yes	No difference
Rotate/pan/zoom/fit to screen	Yes	Yes	No difference
Image display operations	Flip horizontal, vertical Rotate left, right Reset Magnification Scroll Layout 1x1 -3x3 Thumbnails left, right, top, bottom	Flip horizontal, vertical Rotate left, right Clear transform Magnification Scroll Layout 1x1 –3x3 Thumbnails left, right, top, bottom	No difference

	PET fusion Volumetric rendering	PET Fusion Volumetric rendering	
Measurement functions	Line, angle between lines, polyline, area, elliptical area, polygonal area, edit, delete	Line, angle, area,	Medilab has a subset of measurement functions
Annotations	Text	Text	No difference
Report Generation	Yes	Yes	No difference
Print reports	PDF	PDF	No difference
Export	Yes	Yes	No difference
Export reports to CD	No	Yes	No difference
Share function	Yes	Yes	No difference
DICOM Windowing	Yes	Yes	No difference
Low Pass Filter	Yes	No	
Imaging modalities	US, CT, MRI, XRay, PET	US, CT, MRI, XRay, PET	No difference
Communications	DICOM	DICOM	No difference
Operating System for Diagnostic Viewing	Windows, Linux, Mac	Windows, Linux, Mac	No difference
Browser supported	Edge, Firefox, Chrome	Edge, Firefox, Chrome	No difference
Mobile Device Support for Viewing	No	No	No difference
Transfer/Storage/Display of Medical images	Yes	Yes	No difference
Network access	Connects to existing PACS	Connects to existing PACS	No difference

Product comparison to reference predicate devices

Feature	IMPLANTER DENTAL PLANNING SOFTWARE	aPROMISE X	MEDILAB	Comparison to predicates
K#	K173083	K220590	K221065	N/A
Intended Use	Implanter Dental Planning Software is a prescription use software used by dentist and dental lab technicians for the visualization and image segmentation of DICOM data from medical scanners such as CT. The software aids the users in	aPROMISE is intended to be used by healthcare professionals and researchers for acceptance, transfer, storage, image display, manipulation, quantification and reporting of digital	The 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	Similar to K220590

	the creation of 3D models of oral maxillofacial region and in planning dental surgical treatments and placement of dental implants	medical images. The system is intended to be used with images acquired using nuclear medicine (NM) imaging, using PSMA PET/CT. The device provides general Picture Archiving an Communications System (PACS) tools as well as a clinical application for oncology including marking of regions of interest and quantitative analysis.	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 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.	
DICOM image loading and visualization	Yes	Yes	Yes	No difference
Patient search data	Yes	Yes	Yes	No difference
User authentication	Yes	Yes	Yes	No difference
Rotate/pan/zoom/fit	Yes		Yes	No difference
Image operations	Yes	Yes	Yes	No difference
Measurement functions	Line, angle between lines, polyline, area, elliptical area, polygonal area, edit, delete	Yes	Line, angle, area,	Similar to Implanter (subset of measurements)
Report Generation	Yes	Yes	Yes	No difference
DICOM Windowing	Yes	Yes	Yes	No difference
Low Pass Filter	Yes	--	No	Difference
Imaging modalities	CT	PET, CT	US, CT, MRI, XRay, PET	No difference
Communications	DICOM	DICOM	DICOM	No difference
Operating System	Windows, Linux, Mac	Windows or mac OS with Chrome browser	Windows, Linux, Mac	No difference
Browser supported	Edge, Firefox, Chrome	Chrome	Edge, Firefox, Chrome	No difference

Evaluation of similarities and differences:

- MediLab and ZeeroMED View 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. Medilab has similar performance metrics in terms of accuracy as compared to the reference device IMPLANTER. Medilab has also similar PET/SPECT/ SUV functionality as the aPROMISE X device cleared under K220590.
- Differences between both systems consist in user interface layout, navigation, icon coloring and overall system presentation. MediLab provides the functionality to export reports to CD. The primary predicate has a low pass filter functionality which Medilab does not offer. Medilab has a subset of measurements compared to the primary predicate devices. These differences do not impact safety or effectiveness of the Medilab system.

Conclusion:

The subject device has similar technology characteristics and has similar intended use and functionality as the predicate and reference devices. 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 MediLab system 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, Medilab is substantially equivalent to the predicate that is currently marketed for the same intended use.