O3 Enterprise SRL
℅ Jorge Millan, Ph.D.
Regulatory Affairs Manager
Sigma Biomedical
7600 NW 69th Avenue
MEDLEY FL 33166

May 5, 2020

Re: K200546
Trade/Device Name: ZeeroMED View
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: March 6, 2020
Received: March 6, 2020

Dear Dr. 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); 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K200546

Device Name

ZeeroMED View

Indications for Use *(Describe)*

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.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K200546

510(K) Summary

Submitter Information

Submitter	O3 ENTERPRISE SRL Padriciano 99, 34149, Trieste, Italy
Contact:	Jorge Millan, PhD Sigma Biomedical 7600 NW 69th Avenue, Medley FL 33166, USA
Telephone number	(786) 416-5587
Fax number	(305) 328-4511
E-mail	sigmabiomedical@gmail.com
Date prepared:	February 21, 2020

Subject Device Name

Trade/Proprietary Name:	ZeeroMED View
Regulation Number:	892.2050
Regulation Name:	Picture Archiving and Communication System
Product Code:	LLZ
Class	II
Panel	Radiology

Predicate Devices

Predicate Devices:	MedDream
Regulation Number:	892.2050
Regulation Name:	Picture Archiving and Communication System
Product Code:	LLZ
Class	II
Panel	Radiology

Device Description:

The ZeeroMED View Software, or ZeeroMED View, 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. ZeeroMED View 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. ZeeroMED View 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:

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.

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

Predicate Devices

The O3 ENTERPRISE system is equivalent to the MEDDREAM Picture Archiving and Communications system by Softneta UAB cleared under K162011.

Comparison with the Predicate Devices [21 CFR 807.92(a) (6)]: ZeeroMED View is comparable with and substantially equivalent to MedDream Picture Archiving and Communications 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	ZeeroMED View	MedDream
K#		K162011
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.	MedDream is a software medical imaging system used to receive DICOM images, scheduling information and textual reports, organize and store them in an internal format, and to make that information available across a network via web and customized user interfaces. Software is intended for use as a diagnostic, review, and analysis tool by trained professionals such as radiologists, physicians, clinicians. Contraindications: The MedDream is not intended for the acquisition of mammographic image data and is meant to be used by

	Contraindications: The ZeeroMED View is not intended for the acquisition of mammographic image data and is meant to be used by qualified medical personnel.	qualified medical personnel only who are qualified to create and diagnose medical image data.
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 Reset 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 between lines, polyline, area, elliptical area, polygonal area, edit, delete	Line, angle, polyline, area, volume, ellipse, Cobb angle, calibration line, VTI Show angles, edit, delete
Annotations	Text	Text
Report Generation	Yes	Yes
Print reports	PDF	PDF
Export	Yes	Yes
Share function	Yes	Yes
DICOM Windowing	Yes	Yes
Low Pass Filter	Yes	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:

- ZeeroMED View and MedDream 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.
- Differences between both systems consist in user interface layout, navigation, icon coloring and overall system presentation. In addition, MedDream provides additional functionality such as volumetric measurements.

Conclusions:

The subject device has similar technology characteristics and has the similar intended use and functionality as legally marketed 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 ZeeroMED View 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, ZeeroMED View is substantially equivalent to the predicate that is currently marketed for the same intended use.