Singular Health Pty. Ltd.
℅ James Hill
Chief Operating Officer
3/26 Railway Road
Subiaco, Western Australia 6008
AUSTRALIA

Re: K222470 October 25, 2022
Trade/Device Name: 3Dicom MD
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: August 11, 2022
Received: August 16, 2022

Dear James Hill:

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,

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)*

K222470

Device Name:

3Dicom MD

Indications for Use:

3Dicom MD 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.

3Dicom MD displays and manages diagnostic quality DICOM images.

3Dicom MD is not intended for diagnostic use with mammography images. Usage for mammography is for reference and referral only.

3Dicom MD is not intended for diagnostic use on mobile devices.

Contraindications: 3Dicom MD 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

K222470

Submitter information

Submitter	**Singular Health Pty Ltd** 3/26 Railway Road Subiaco 6008 AUSTRALIA
Contact person	James Hill Chief Operating Officer Singular Health jhill@singular.health (alternative: singularhealth@outlook.com) P: +61 8 1300 167 795
Date prepared	18-Oct-2022

Subject device information

Trade/Proprietary name	**3Dicom MD**
Model number	V3.1.0
Regulation number	892.2050
Regulation name	Medical Image Management and Processing System
Product class	LLZ
Review panel	Radiology
Class	II

Predicate device information

Trade/Proprietary name	ZeeroMED View (K200546)
Regulation number	892.2050
Regulation name	Picture Archiving and Communications System
Product class	LLZ
Review panel	Radiology
Class	II

Reference device information

Trade/Proprietary name	OsiriX MD™ (K101342)
Regulation number	892.2050
Regulation name	Picture Archiving and Communications System
Product class	LLZ
Review panel	Radiology
Class	II

Device description

3Dicom MD is a software application developed to focus on core image visualization functions such as 2D multi-planar reconstruction, 3D volumetric rendering, measurements, and markups. 3Dicom MD also supports real-time remote collaboration, sharing the 2D & 3D visualization of the processed patient scan and allowing simultaneous interactive communication modes between multiple users online through textual chat, voice, visual aids, and screen-sharing.

Designed to be used by radiologists and clinicians who are familiar with 2D scan images, 3Dicom MD provides both 2D and 3D image visualization tools for CT, MRI, and PET scans from different makes and models of image acquisition hardware.

Indications for use

3Dicom MD 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 the patient's image, demographic and report information.

3Dicom MD displays and manages diagnostic quality DICOM images.

3Dicom MD is not intended for diagnostic use with mammography images. Usage for mammography is for reference and referral only.

3Dicom MD is not intended for diagnostic use on mobile devices.

Contraindications: 3Dicom MD is not intended for the acquisition of mammographic image data and is meant to be used by qualified medical personnel.

Comparison table

Comparison of 3Dicom MD with the predicate, ZeeroMED View, is presented in the below table.

Features	**3Dicom MD**	**ZeeroMED View (Predicate)**
K number	K222470	K200546
Class	II	II
Regulation number	21 CFR 892.2050	21 CFR 892.2050
Regulation name^	Medical Image Management and Processing System	Picture archiving and communications system
Product code	LLZ	LLZ
Indications for use	3Dicom MD 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,	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

	demographic and report information. 3Dicom MD displays and manages diagnostic quality DICOM images. 3Dicom MD is not intended for diagnostic use with mammography images. Usage for mammography is for reference and referral only. 3Dicom MD is not intended for diagnostic use on mobile devices. Contraindications: 3Dicom MD is not intended for the acquisition of mammographic image data and is meant to be used by qualified medical personnel.	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.
Users	Trained healthcare professionals	Trained healthcare professionals
Mammographic diagnostic use	No	No
Imaging modalities	CT MRI PET	CT MRI PET Xray US
Communications	DICOM	DICOM
Installation	Local computer / Server	Cloud
Operating system for diagnostic viewing	Windows Mac	Web-based (Windows, Mac, Linux)
User authentication (unique login)	Yes	Yes
Access to DICOM studies	Connect to existing onsite PACS Local computer/server USB drives / CD / DVD	Connect to existing PACS
Patient study search function	Yes	Yes
Basic visualisation tools	Grayscale display Rotate Pan Zoom Magnification Fit to screen Scroll Flip horizontal / vertical Axial / coronal / sagittal views Cross-hair Adjustable windowing (WW/WL) HU (Hounsfield Unit) Slice indicator Reset	Grayscale and colour display Rotate Pan Zoom Magnification Fit to screen Scroll Flip horizontal / vertical Axial / coronal / sagittal views Cross-hair Adjustable windowing (WW/WL) HU (Hounsfield Unit) Slice indicator Reset
Advanced tools	Volume rendering (3D) MPR	Volume rendering (3D) MPR PET fusion
Measurements	2D only Line Angle / Cobb angle	2D only Line Angle between lines

	Polyline Area (elliptical, polygonal) Edit / Delete	Polyline Area (elliptical, polygonal) Edit / Delete
Annotations	Yes	Yes
Screenshot	Yes	Yes
Video & audio recording	Yes	Unknown
Anonymization function	Yes	Yes
Studies comparison	No	Yes
Share function (email)	Yes	Yes
Collaboration function (online meeting)	Yes	Yes
Export functions	Yes JPEG / PNG .nii / .nrrd / .hdr / .img / .mhd MP4	Yes
Report generation	No	Yes

^The Regulation 21 CFR 892.2050 name has been amended in April 2021

Performance data

Software verification and validation activities for 3Dicom MD were performed in accordance with FDA guidance *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices* (May 2005), including measurement accuracy and usability tests.

3Dicom MD is considered a “moderate" level of concern.

Singular Health has implemented security features for the device and data protection. Cybersecurity requirements, risk analysis, and mitigation was addressed in accordance with FDA guidance *Content of Premarket Submission for Management of Cybersecurity in Medical Devices* (Oct 2014).

No clinical testing was required to demonstrate safety or effectiveness for the subject device as the device's non-clinical (bench) testing was sufficient to support the intended use of the device.

The measurement accuracy for the length, angle, and area features was validated using Digital Reference Objects compared against the known values or the reference device. The Digital Reference Objects (n=81 test cases) created were representative of the clinical range typically encountered in radiology practice (1-180 mm). Inter-operator error (reproducibility), and intra-operator error (repeatability) were assessed.

Measurement accuracy	
Length (>10 mm)	99.3%
Length (1-10 mm)^	98.8%
Area	99.52%
Angle	99.46

^The tested accuracy for the lowest clinical range (1-10mm) was found to be slightly inferior (98.8%), due to the resolution of the input scan (Row Count and Column Count) and resolution of the screen.

Evaluation of similarities and differences

3Dicom MD and the predicate have the same intended use, main images functionalities, and collaborative/sharing functions. In term of use and functions, both systems access, upload, and display DICOM images and metadata, and provide tools and resources to trained healthcare professionals for study review and analysis.

The main differences between both systems consist of the system access (local installation for 3Dicom MD versus web-based for the predicate). There are also minor differences in layout and some image functionalities. These differences do not present different questions of safety or effectiveness than the predicate device because safety and cybersecurity requirements have been defined and implemented, then tested and verified by a cybersecurity assessment, and the clinical functionalities have been tested by usability testing involving trained healthcare professionals.

Conclusions

3Dicom MD and the predicate have the same intended use and indications, technological characteristics, and principles of operation. There are no differences between the devices that affect the usage, safety and effectiveness. The non-clinical performance data and software verification and validation demonstrate that 3Dicom MD performs comparably to and 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, 3Dicom MD is substantially equivalent to the predicate.