January 8, 2026

Singular Health Pty, Ltd.
Andre Marchezini Rocha
Chief Quality Officer
E3/661 Newcastle St.
Leederville, 6007
Australia

Re: K253784
Trade/Device Name: 3DICOM MD Cloud
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: November 17, 2025
Received: November 26, 2025

Dear Andre Marchezini Rocha:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*

K253784

Device Name

3DICOM MD Cloud

Indications for Use *(Describe)*

3DICOM MD Cloud is intended for use as a diagnostic and analysis tool for multi-modality medical images and their associated reports and information, enabling qualified healthcare professionals from hospitals, imaging centres, radiologists, and reading practices to view patient images, documents, and related data. 3DICOM MD Cloud enables qualified users to manipulate medical images, create markups, and perform measurements using a range of tools.
3DICOM MD Cloud is not intended for diagnostic use with mammography images. Usage for mammography is for reference and referral only. 3DICOM MD Cloud is not intended for diagnostic use on mobile devices.

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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3DICOM MD Cloud
510(k) Summary

Submitter information

Submitter	**Singular Health Pty Ltd** E3/661 Newcaste St Leederville WA 6007 AUSTRALIA
Contact person	Andre Marchezini Rocha Chief Quality Officer Singular Health amarchezini@singular.health P: +61 1300 167 795
Date prepared	10 November 2025

Subject device information

Trade/Proprietary name	**3DICOM MD Cloud**
Model number	v1.0.0
Regulation number	892.2050
Regulation name	Medical Image Management and Processing System
Product class	LLZ
Review panel	Radiology
Class	II

Device Description

3DICOM MD Cloud is a software as a medical device that provides diagnostic viewing and analysis of multi-modality DICOM images in a secure, web-based, cloud/server-hosted environment. Authorized users access studies from site-provisioned cloud storage sources and perform 2D multi-planar viewing (MPR) and 3D visualization, apply window/level and other standard adjustments, make 2D measurements and annotations, generate a DICOM-structured report summarizing tracked measurements, and export snapshots/measurement tables. The device does not generate diagnoses or provide automated clinical interpretation.

Indications for Use

3DICOM MD Cloud is intended for use as a diagnostic and analysis tool for multi-modality medical images and their associated reports and information, enabling qualified healthcare professionals from hospitals, imaging centres, radiologists, and reading practices to view patient images, documents, and related data. 3DICOM MD Cloud enables qualified users to manipulate medical images, create markups, and perform measurements using a range of tools.

3DICOM MD Cloud is not intended for diagnostic use with mammography images. Mammography usage is for reference and referral only. 3DICOM MD Cloud is not intended for diagnostic use on mobile devices.

Predicate Devices

Primary predicate (FlexView Diagnostic)

Item	Detail
Device name	FlexView Diagnostic
510(k) number	K233226
Manufacturer	Radical Imaging LLC
Regulation number	21 CFR 892.2050
Regulation name	Medical Image Management and Processing System
Product code	LLZ

Reference device (3Dicom MD)

Item	Detail
Device name	3Dicom MD
510(k) number	K222470
Manufacturer	Singular Health Pty Ltd
Regulation number	21 CFR 892.2050
Regulation name	Medical Image Management and Processing System
Product code	LLZ

The primary predicate supports intended use and technological characteristics for a web-based diagnostic viewer; the reference predicate supports technical lineage from the sponsor's previously cleared client-installed application. The predicates have not been subject to a design-related recall.

Predicate Device Comparison

Feature	3DICOM MD Cloud (Subject)	FlexView Diagnostic (Primary Predicate)	Comments
Intended Use	Diagnostic viewing and analysis of multi-modality medical images with associated information; supports mark-ups, measurements, applicable 3D visualization; not for diagnostic use with mammography; not for diagnostic use on mobile devices.	Diagnostic viewing and analysis of multi-modality medical images with associated information; supports mark-ups, measurements, 3D visualization; not for diagnostic use with mammography; not for diagnostic use on mobile devices.	Same intended use and limitations.
Mammographic Use	No (diagnostic)	No (diagnostic)	Same
DICOM Image Loading and Visualization	Yes (loads DICOM objects from 3DICOM cloud storage).	Yes	Both load and visualize DICOM images.
Can Search Patient Study Data	Yes (within provisioned 3DICOM cloud study lists).	Yes	Same
User Authentication	Yes	Yes	Same
Window/Level Adjustments	Yes.	Yes	Same

Control the Image View: Rotate, Pan, and Zoom	Yes	Yes	Same
Image Display Operations	Flip horizontal, vertical Rotate left, right Reset Magnification Scroll Layout 1x1 -3x3 Thumbnails left, right, top, bottom Volumetric rendering	Flip horizontal, vertical Rotate left, right Reset Magnification Scroll Layout 1x1 -3x3 Thumbnails left, right, top, bottom Volumetric rendering	Same
2D Measurement Functions Included	Line Poly-line Bi-directional, Rectangle Angle Freehand ROI Circle Ellipse Cobb angle	Line Poly-line Bi-directional, Rectangle Angle Freehand ROI	Subject includes, circle, ellipse and Cobb angle; predicate does not. However this does not raise any concerns as the reference predicate device supports these measurement functions.
Text Annotations	Yes	Yes	Same
Report Generation	Yes	Yes	Same
Print Reports	PDF	PDF	Same
Export	Yes	Yes	Same
Share Function	Yes	No	The subject device allows saving and exporting of sessions to other users.
DICOM Windowing	Yes	Yes	Same
Imaging Modalities	CT MRI XR US PET	CT MRI XR US	Subject additionally supports PET.
Communications	API (cloud-storage ingest via 3DICOM cloud)	DICOM/DICOMweb and PACS Connection	Principal architectural difference.
Operating Systems Supported	Windows, macOS, Linux (via supported desktop browsers).	Windows, macOS, Linux (via supported desktop browsers).	Both are desktop browser viewers; OS-agnostic via the browser.
Web Browsers Supported	Chrome, Edge, Safari, Firefox (desktop).	Chrome, Edge, Safari, Firefox (desktop).	Same
Mobile Device Support	No	No	Same
Store, Display, and Transfer Medical Images	Yes	Yes	Same
Connects to Existing PACS	No (ingest via 3DICOM cloud storage only; no direct PACS/DICOM network).	Yes (institutional PACS/VNA via DICOM/DICOMweb).	Key architectural difference.

Reference Predicate - 3Dicom MD

Reference predicate—3Dicom MD (K222470). 3Dicom MD is a locally installed desktop viewer (Windows/macOS) that connects to local/PACS/removable DICOM sources; supports CT, MR, and PET; includes ellipse, circle, and Cobb angle tools with ROI statistics; and offers broad image/research exports (e.g., JPEG/PNG, NIfTI/NRRD). It supports saving and exporting of sessions to other users and includes desktop collaboration/recording features. 3Dicom MD and 3DICOM MD Cloud follow the same master validation protocol, with the subject device adapted for the cloud environment. Cited solely for technical lineage; differences are chiefly deployment/workflow and do not raise new questions of safety or effectiveness.

Performance Testing

Software verification and validation activities for 3Dicom MD Cloud were performed in accordance with FDA guidance, *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices* (June 2023), including measurement accuracy and usability tests.
The documentation provided in this application meets the Basic level definition.

Singular Health has implemented security features for the device and data protection. Cybersecurity requirements, risk analysis, and mitigation were addressed in accordance with FDA guidance *Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submission* (June 2025).

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.

Evaluation of Similarities and Differences

- **Intended use/indications:** Similar to the primary predicate, with the same mammography and mobile-device limitations.
- **Technological characteristics:** All devices are medical image management and processing systems (21 CFR 892.2050, LLZ). The subject and the primary predicate are based on the same open-sourced software and share a similar code base.
- **Principles of operation:** Load → display → manipulate → measure/annotate → export are comparable across the devices/web browsers.

Observed differences (e.g., specific UI layout, omission of some measurement tools, additional modality support (PET scan), integration with user account management, sharing of saved sessions, etc) do not raise new questions of safety or effectiveness**.** They are mitigated by software V&V, risk management, usability evaluation (as applicable), interoperability checks, and cybersecurity controls.

Conclusion

Based on the identical intended use/indications, comparable technological characteristics and principles of operation, and the demonstrated non-clinical performance, 3DICOM MD Cloud is substantially equivalent to the identified predicate device.