FDA 510(k) submission for 3DICOM MD™ Cloud

HIGHLIGHTS

- Singular Health has submitted a 510(k) premarket notification to the U.S. Food and Drug Administration (FDA) for 3DICOM MD™ Cloud, the next-generation version of its FDA-cleared 3DICOM MD™ Viewer.
- 3DICOM MD™ Cloud expands imaging capability to include additional modalities such as X-ray and ultrasound, alongside the existing CT, MRI and PET.
- The platform introduces clinically optimised workflow and interface enhancements, developed in collaboration with Dr Ronny Low, to support more intuitive clinical use.
- 3DICOM MD™ Cloud provides a browser-based, cloud-native solution for retrieval, management and viewing of medical images, enabling rapid access and collaboration across care teams.
- The enhanced cloud architecture establishes a scalable foundation for Singular Health's AI marketplace, supporting a "one-stop-shop" platform for sharing, viewing, storing and analysing medical images.

Singular Health Limited (ASX: SHG) is pleased to announce the submission of a 510(k) premarket notification to the United States Food and Drug Administration for 3DICOM MD™ Cloud, an advanced version of the Company's existing software-as-a-medical-device (SaMD) 3DICOM MD™ Viewer.

3DICOM MD™ received FDA clearance in 2022 and was originally designed to view standard 2D medical images in DICOM format, primarily CT, MRI and PET, into fully interactive 3D models for clinical review and collaboration. Building on this foundation, 3DICOM MD™ Cloud has been developed to broaden clinical functionality, modernise workflow, and enable scalable deployment through the cloud.

What is new in 3DICOM MD™ Cloud

3DICOM MD™ Cloud delivers a substantial evolution of the Company's FDA-cleared 3DICOM MD Viewer, extending capability and improving clinical usability. The advanced platform now supports additional imaging modalities, including X-ray and ultrasound, alongside existing CT, MRI and PET visualisation, widening its applicability across clinical settings. In close collaboration with Dr Ronny Low, Singular Health has also integrated direct clinical inputs into the development process, resulting in a more clinician-friendly interface and workflow designed to better reflect day-to-day use in multidisciplinary care.

Built on a solid, cloud-native technical foundation, 3DICOM MD™ Cloud is engineered to scale with Singular Health's future AI roadmap, underpinning a one-stop-shop marketplace for the sharing, viewing, storing and AI-enabled analysis of medical images. The move to secure browser-based access further simplifies retrieval, management and viewing, enabling clinicians to work efficiently across sites without the need for complex dedicated desktop installations.

Together, these enhancements create a faster, more integrated collaboration and sharing environment, supporting rapid case review, improved multidisciplinary decision-making, and enhanced continuity of care.

Figure 1. 3DICOM MD™ Cloud enabling interoperability and browser-based immersive viewing of standard medical images.

Next Steps & Implications

After acceptance, the FDA will move to substantive review with a target decision timeframe of around 90 FDA days for a traditional 510(k). This 90-day clock can pause if the FDA requests additional information and restarts upon the Company addressessing such requests.

A successful outcome would result in FDA clearance confirming substantial equivalence to the appropriate predicate device, enabling marketing and clinical use of 3DICOM MD™ Cloud in the United States. U.S. Food and Drug Administration Clearance would extend Singular Health's U.S. regulatory footprint beyond the existing 3DICOM MD™ Viewer, support the Company's strategy to scale recurring revenue through the adoption from healthcare organsations and providers, and validate the platform's cloud-native foundation for AI-enabled modules and marketplace expansion.

Additionally, achieving clearance would strengthen Singular Health's business case for reducing unnecessary duplicate imaging by enabling a hardware-free, browser-based cloud platform that eliminates complex desktop and IT installations, reduces implementation friction, and improves usability and timely access to 3D medical imaging for healthcare providers.

Singular Health's Chief Quality Officer, Andre Rocha, commented on the milestone:

"Submitting our 510(k) for 3DICOM MD™ Cloud is a major step in advancing Singular Health's regulatory pathway for the next-generation of image visualisation and collaboration applications. This submission reflects a rigorous quality and risk-management process, and positions the Company to deliver a clinically enhanced, cloud-based platform aligned with U.S. regulatory expectations. We are proud of the team's work in reaching this important milestone."

The Company will continue to work with the FDA during its review of the submission and will keep the market informed of material developments in line with its continuous disclosure obligations.

This announcement is authorised for release by the Board of Directors for the Company.

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About Singular Health

Singular Health is a Western Australian, ASX-listed (ASX: SHG) medical technology company on a mission to create a seamless and integrated healthcare ecosystem where the full value of medical imaging records is unlocked, enabling universal access and promoting interoperability to maximise patient outcomes.

Singular Health's 3Dicom software solutions empower patients and practitioners to better visualise, communicate, and understand medical imaging data. 3Dicom MD® is cleared for diagnostic use in the United States. To learn more, visit https://singular.health and https://investors.singular.health/