FDA 510(k) Clearance for 3DICOM MD® Cloud Strengthens U.S. Commercial Strategy

HIGHLIGHTS

- Expansion of Singular Health's regulated product portfolio with FDA 510(k) clearance for 3DICOM MD® Cloud, a Class II Software as a Medical Device (SaMD), building on the Company's prior FDA clearance for the desktop 3DICOM MD® software in October 2022.
- Accelerated FDA review completed in 40 days, well ahead of the typical ~90 calendar day timeframe, reflecting a robust regulatory submission and comprehensive testing and validation.
- Cloud-based, browser-enabled deployment removes the need for hardware and complex desktop or IT installations, lowering adoption barriers and improving usability for healthcare organisations.
- Expanded imaging modality support, now including X-ray and ultrasound in addition to CT, MRI and PET, materially widening clinical applicability and potential use cases.
- Significant market opportunity: estimated US$16.5B TAM for reducing duplicate imaging in the U.S. across PET, CT, MRI, X-ray and ultrasound.

Singular Health Limited (ASX: SHG) ("Singular Health" or the "Company") is pleased to announce that the U.S. Food and Drug Administration (FDA) has granted 510(k) clearance for 3DICOM MD® Cloud, the Company's cloud-based evolution of its FDA-cleared 3DICOM MD® software.

3DICOM MD® Cloud has been cleared as a Class II Software as a Medical Device (SaMD), enabling marketing and clinical use of the platform in the United States. The clearance represents a significant regulatory milestone and further strengthens Singular Health's U.S. market strategy by expanding its regulated product portfolio.

This clearance represents a significant step forward for Singular Health as it expands the Company's portfolio of regulated products and strengthens its U.S. commercial strategy.

Singular Health Managing Director & CEO, Denning Chong, said:

"This clearance, achieved well ahead of time, represents a major milestone for Singular Health and our U.S. strategy. 3DICOM MD® Cloud removes many of the traditional barriers to adoption by eliminating the need for hardware and complex desktop installations, while expanding modality coverage to include X-ray and ultrasound. This positions the Company to scale faster and drive greater impact in reducing duplicate imaging."

Regulatory pathway and review outcome

The 510(k) submission leveraged the Company's prior FDA clearance for the desktop version of 3DICOM MD®, which was granted in October 2022, enabling the Company to build on an established and regulated foundation for image viewing and clinical use.

Confirmation of lodgement was received on 29 November 2025. While a traditional FDA review pathway is typically around 90 calendar days, the Company is pleased that in this instance the review process was concluded in 40 days, demonstrating the quality and robustness of the submission and reflecting the rigorous testing and validation completed for 3DICOM MD® Cloud.

Significance of the FDA clearance

This FDA clearance represents a significant step forward for Singular Health as it expands the Company's portfolio of regulated products and strengthens the commercial proposition for large healthcare organisations. By delivering a cloud-based solution that removes the need for complex desktop and IT installations, 3DICOM MD® Cloud is designed to reduce adoption barriers, improve usability, and facilitate timely access to 3D medical imaging across sites and multidisciplinary teams.

Building on the existing capabilities of the FDA-cleared 3DICOM MD® Viewer, 3DICOM MD® Cloud expands imaging modality support to include X-ray and ultrasound, alongside CT, MRI and PET, broadening applicability across additional clinical pathways and strengthening the Company's ability to help reduce unnecessary duplicate imaging through improved sharing and access to medical imaging records.

Market opportunity

The Company estimates a significant U.S. opportunity to address unnecessary duplicate imaging, with a total addressable market (TAM) of approximately US$16.5B. This estimate is based on direct imaging costs of US$236.5B and an estimated 7.7% duplicate occurrence across PET, CT, MRI, X-ray and ultrasound[1]. Importantly, X-ray and ultrasound were not supported in the previously cleared desktop version but are included in 3DICOM MD® Cloud, materially expanding the range of clinical pathways and use cases the platform can support and broadening the Company's addressable market.

The Company will continue to 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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[1] The estimated duplicate imaging rate is informed by peer-reviewed research, including Bailey et al., *Health Information Exchange and the Frequency of Repeat Medical Imaging*, American Journal of Managed Care (2013), which reported a repeat imaging rate of approximately 7.7% in a large U.S. cohort. The Company's estimated TAM of approximately US$16.5B is based on an internal market analysis applying modality-specific duplicate rates (approximately 4%–8.5%) to estimated annual U.S. scan volumes across X-ray, CT, MRI, PET and ultrasound, multiplied by average per-scan costs for each modality.

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/