

Singular Health Group Ltd: SHG

ASX Announcement

27th October 2022

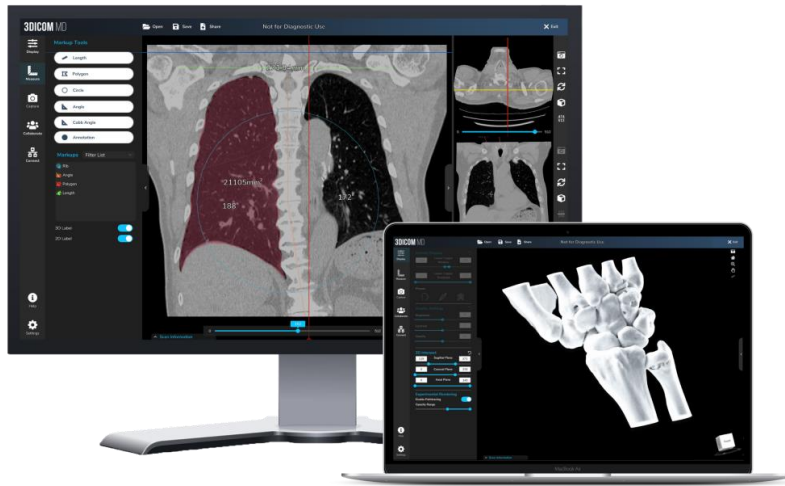


Figure 1: 3Dicom MD™ software operates across both Windows and Mac operating systems with 2D & 3D visualisation

3Dicom MD software receives 510(k) clearance from US Food and Drug Administration (FDA)

- Singular Health's 3Dicom MD software has been cleared as a Class II Software-as-a-Medical Device (SaMD) by the United States Food and Drug Administration.
- 510(k) clearance enables commercial launch into United States' medical imaging software market valued at \$USD885.5 million per annum¹.
- Certifies a key element to the company's "Scan to Surgery[®]" strategy.

27 October 2022 – Medical technology company Singular Health Group Ltd (ASX: SHG) ("Singular Health", or "the Company") is pleased to announce it has received 510(k) clearance from the United States Food and Drug Administration (FDA) for its '3Dicom MD' Software-as-a-Medical-Device (SaMD) product which is designed for use by medical practitioners to collaboratively visualise standard CT/MRI and PET scans in 2D & 3D in real-time with built-in voice and text chat, and remote control functionality.

On the 16th of August 2022, Singular Health received confirmation of lodgement from the FDA of its 510(k) submission for 3Dicom MD, a Class II Software-as-a-Medical Device. 510(k) submissions typically target a nominal 90 calendar day review period and the receipt of Singular Health's first ever 510(k) clearance within this period demonstrates the high quality of the submission by Singular Health's entire team and regulatory consultants.

The FDA clearance of 3Dicom MD represents a significant step forward in Singular Health's commercialisation plan as it enables the commercial launch of our software into the United States where the medical imaging software market was valued at USD\$885.5M in 2020¹.

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Singular Health intends to commercialise 3Dicom MD in the US market through a combination of enterprise partnerships and distribution agreements and through the Company’s direct online sales channel, 3dicomviewer.com to target individual practitioners, larger scale medical practices, and general purchasing organisations (GPOs).

Singular Health’s CEO and Managing Director, Thomas Hanly, said:

“Receipt of our first FDA 510(k) diagnostic certification of 3Dicom MD™, is a significant commercial achievement at Singular Health. It provides a regulatory moat, external validation of our software, and access to the lucrative US medical diagnostic market. Furthermore, 3Dicom MD™ is a key element in the company’s Scan to Surgery® strategy providing pre-surgical diagnostic review, planning and patient education. I’d like to take this opportunity to congratulate our regulatory team, developers, and consultants on their incredible work in preparing and lodging the submission. I’m excited for 2023 as we focus on the commercialisation of our 3Dicom software.”

Ends

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

For further information contact:

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About Singular Health:

Singular Health Group Limited (ASX: SHG) is a medical technology company that empowers practitioners and patients via personalised surgical planning solutions that drive better health outcomes.

Singular Health has developed a proprietary Volumetric Rendering Platform (VRP) that leverages existing 2D radiological images to generate fully immersive patient-specific 3D/VR models.

Complementing its VRP technology, Singular Health has acquired Virtual Surgical Planning software and a 25% stake in medical-grade 3D printing company Additive Engineering. These investments represent key milestones in Singular Health’s efforts to commercialise its ‘Scan to Surgery’ initiative, a world-first vertically integrated platform that revolutionises the planning and execution of personalised surgical procedures.

A successful full-scale commercialisation of this end-to-end personalised surgical planning platform will give Singular Health the capability to penetrate a multi-billion-dollar global market opportunity in the medical visualisation and additive manufacturing spaces.

With Singular Health, practitioners are empowered by having the ability to collaborate with producers of patient-specific medical components in real-time while patients benefit from having access to easily comprehensible and enhanced medical information.

To learn more, please visit: www.singular.health

¹ <https://www.researchandmarkets.com/reports/4805205/medical-image-analysis-software-global-market>

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