

Singular Health Group Ltd: SHG

ASX Announcement

9th November 2022

Singular Appoints US-Agent & Founding 3Dicom Partner Program Member

- Singular Health's 510(k) diagnostic clearance from the United States' Food & Drug Administration (FDA) for 3Dicom MD™ recently granted, allowing for sale in the US
- Kelyniam Global, a US-based patient-specific medical device manufacturer, to be engaged as Singular Health's US-based agent for FDA, final regulatory step pre-sales
- CG1 Solutions joins Partner Program as inaugural US member to promote 3Dicom MD™

9 November 2022 – Medical technology company Singular Health Group Ltd (ASX: SHG) ("Singular Health", or "the Company") is pleased to announce the appointment of Kelyniam Global Inc (OTC: KLYG) ("Kelyniam") as the Company's US-based agent, a key appointment and important pre-requisite to satisfy the final regulatory requirement, prior to Singular Health making sales in the US.

Singular Health is also excited to announce that CG1 Solutions, a Florida-based, well established medical IT consulting services company providing solutions to US hospitals, has joined the recently formed 3Dicom Partner Program. CG1 Solutions will shortly commence promoting the diagnostic 3Dicom MD™ software for sale into US hospitals.

These key appointments follow presentations by Singular Health's COO, James Hill, at the Southern Neurosurgical Society (SNS) 2022 Conference in March, and American Association of Neurological Surgeons (AANS) in May, and by Dr Guan Tay, Executive Director of Research and Innovation, and Dr Martina Mariano, Global Partnerships Manager, at the MedTech conference in Boston in October, highlighting the success of Singular's ongoing outreach in creating global recognition for the Company and its products.



Figure 1: From left to right, Kelyniam's Marketing Manager, Mr Basiru Sumbundu, Singular Health's COO, Mr James Hill, and Kelyniam's CEO, Mr Ross Bjella at the American Association of Neurological Surgeons tradeshow in May 2022



Figure 2: Singular Health's Global Partnerships Manager, Dr Martina Mariano (left), with Kelyniam's VP of Sales and Strategic Development, Desiree Webb (right) in October 2022

Appointment of US-based Agent – Kelyniam Global

Kelyniam Global Inc, a Connecticut-based medical device manufacturer involved primarily in patient-specific cranial implants, has been selected as the Company's US-based agent due to their current management's recent exceptional track record, highly skilled and flexible team, and strong reputation in the US patient specific implant market.

The appointment of a US-based Agent is required by the FDA for all foreign entities, to act as the in-country point of contact and liaison on regulatory filings, product updates and other requirements, prior to making sales in the US market.

Receptive to new technologies and with a well-established customer base of surgeons and well-incentivised sales force, Kelyniam is also very well positioned to both provide continual feedback on the 3Dicom Surgical software and AI cranial implant tool (under development), 3Dicom MD™ software (now diagnostically certified), and 3Dicom Patient with the soon-to-be-released Mobile App.

Founding Member of Partner Program – CG1 Solutions

CG1 Solutions, a Florida-based IT medical consulting company, has recently joined Singular Health's newly established B2B "3Dicom Partner Program" and will be marketing both the non-diagnostic and diagnostic 3Dicom software offerings to their existing customer base, and conducting joint marketing activities with Singular Health at upcoming tradeshow and conferences.

Singular Health's 3Dicom Partner Program, run by Dr Martina Mariano, will see a focus on engaging with medical device manufacturers and digital health and medical technology companies to promote, market, and integrate Singular Health's 3Dicom software on a global scale, complementing and leveraging the direct-to-consumer channel.

Operating through discounts and commissions, the 3Dicom Partner Program greatly reduces capex requirements for Singular Health to enter the US market, whilst providing strong financial incentives for 3Dicom Partners to actively commercialise the 3Dicom software whilst offering additional benefits through the diversification of their product offerings and ongoing revenue streams.

CG1 Solutions was identified as a founding member of Singular Health's 3Dicom Partner Program based on their shared vision of improving patient-specific outcomes through technologies, along with their existing presence in the US healthcare market providing services to large hospitals and clinics. CG1 Solutions and Singular are currently pursuing opportunities to provide patient education solutions with 3Dicom in US hospitals and clinics. Under the 3Dicom Partner Program, Sales Partners are not currently bound to minimum sales volumes and each party incur their own costs.

Kelyniam's VP of Sales and Strategic Development, Ms Desiree Webb, said:

"As we advance in healthcare solutions, providing physicians with the necessary tools to be efficient, precise and communicate effectively is essential to improving patient care and outcomes. Kelyniam prides itself on being an industry leader in customized medical device technology. The alignment with Singular Health, as the US FDA Registered Agent, serves as another example of our commitment to individualized healthcare in support of positive outcomes in a cost-effective fashion."

CG1 Solution's Managing Partner, Edwin Rivera, said:

"CG1 Solutions is excited to be part of the Singular Health Group partner program here in the United States. Singular Health's technology, particularly the 3Dicom Viewer, provides the next level of interaction and engagement."

"We see this application, which allows MRI and CT scans to be viewed in 3D, as being the new standard in the industry and that is why we are thrilled to be a partner."

Singular Health's CEO, Thomas Hanly, said:

"After engaging with Kelyniam's team on our cranial AI model and various initiatives through 2022, we've witnessed first-hand their deep in-country expertise and particularly the calibre of their Leadership team. We welcome them as our US-agent and will continue to work towards further strengthening the ties between our companies."

"We are also very pleased to be working with CG1 Solutions, Singular Health's first Sales Partner, and are encouraged by their joint vision and feedback on the 3Dicom software. We look forward to working with them to promote 3Dicom Patient, R&D, and MD into the US hospital system to aid in patient education."

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

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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.

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

About Kelyniam Global:

Kelyniam Global Inc. (OTC: KLYG) specializes in the rapid production of custom prosthetics utilizing computer aided design and computer aided manufacturing of advanced medical grade polymers.

The Company develops, manufactures, and distributes custom cranial and maxillo-facial implants for patients. Kelyniam works directly with surgeons, health systems and payors to improve clinical and cost-of-care outcomes.

To learn more, please visit: www.kelyniam.com

About CG1 Solutions:

CG1 (Charlie Golf One) is a Service-Disabled Veteran-Owned Small Business (SDVOSB) information technology firm based in South Florida. We specialize in engaging solutions that empower both enterprise and direct to consumer industries.