

## TGA responds to application for regulatory approval of the Guardian in Australia

**Hydrix Limited** (ASX: HYD) (**Hydrix** or the **Company**) has been advised by the TGA that its current application for regulatory approval to market and distribute the Angel Medical Systems ("AngelMed") Guardian in Australia is not going to be accepted. Hydrix has not yet received formal notice of its decision from the TGA.

### Hydrix and AngelMed's position on the Guardian

- **Australia is one of eight countries where Hydrix has exclusive rights to distribute the Guardian covering a total population of more than 500 million people.** Hydrix has commenced commercialisation of the Guardian in approved markets, including in Singapore and Malaysia, where eight successful implants have been completed.
- **The TGA granted Hydrix until close of business the 27<sup>th</sup> of February 2023 to consider its response.** Hydrix is seeking clarification from the TGA, and during this period, will consider the matters raised and evaluate the alternate pathways and options available to seek a TGA approval.
- **The TGA has advised that in their view,** AngelMed's clinical evidence did not demonstrate that the patient benefits sufficiently outweighed the risks of an implanted device using a pacemaker lead to monitor the heart signal to detect and alarm a patient of a life threatening situation.
- **Hydrix and AngelMed are confident in the safety and efficacy of the Guardian device,** and that the benefits outweigh the risks to improve the current standard of care based on more than 3,450 patient years of safety data and 1,550 patient years of efficacy / performance data.
- **When the US FDA approved the device,** it stated in its decision that the **benefits outweigh the risks**, and that the device *"fills an unmet medical need by providing more effective diagnosis of a life-threatening condition compared to relying on patient symptoms alone."*
- Hydrix confirms the TGA application and information variously provided **included all of the information used to gain regulatory approval** in the USA (June 2021), Singapore (August 2022) and Malaysia (June 2022) where it is now being prescribed to suitable ACS patients.

### TGA outcome does not impact current revenue and earnings

- **Hydrix is a diversified medical device technology company** with three business segments. The ambitious cardiac product distribution business strategy is in its early stages but offers huge potential long term growth opportunities given cardiovascular disease is the leading cause of death globally (31%).
- **Revenue and profits are being generated** from Hydrix product design and engineering services business which grew revenues 24% (\$6.4m v. \$5.1m pcp) and reported a 116% improved EBITDA profit (\$0.17m v. \$1.06m loss pcp) result in the first half of FY23.
- **Hydrix currently has investments in three Services clients (\$3.65m book value).** These maturing early-stage investments in world-first product companies are anticipated to generate material asset revaluation increases in the year ahead as they reach major inflection points.

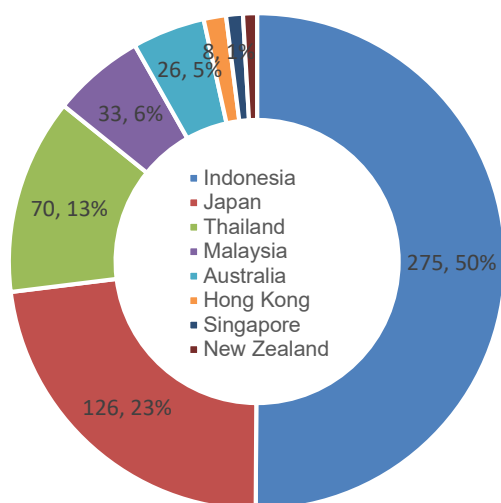
## The AngelMed Guardian – a disruptive device to improve cardiac patient management

Hydrix is working to improve the management of cardiovascular disease for all Australians.

The current standard of care for detecting ACS events and getting patients to treatment is entirely dependent upon patient symptoms – *‘having them, recognising them, and then acting on them in a timely manner’* which research shows is a significant issue and left undiagnosed, long term, leads to poor patient outcomes. *We consider this standard of care – unsatisfactory.*

Angel Medical Systems Guardian is the world’s first and only real-time heart attack alert system, intended for patients who suffer from acute coronary syndrome events. For all the reasons we have advocated for the Guardian, we remain confident in the positive benefits the device offers to high risk ACS patients at risk of a recurrent ACS event.

**The chart below shows the addressable population of the eight countries under exclusive distribution and the regulatory status of markets other than Australia**



Population (in Millions & % of total)  
in Distribution Region

Country / Agency	Appl. Date	Status
USA / FDA	n/a	Approved
Singapore / HSA	16-Aug-21	Approved
Malaysia / MOH	27-Dec-21	Approved
Thailand / Thai FDA	12-Oct-21	In process
New Zealand / MMDSA	11-Aug-21	WAND notified
Hong Kong	-	In process
Japan	-	In process
Indonesia	-	In planning

**Mr Gavin Coote, Hydrix Executive Chairman commented:**

*"The TGA's view came as a surprise and was not the outcome we were expecting, given FDA approval endorsed the safety and efficacy of the Guardian device, concluding the benefits outweighed the risks, based on the same information provided to the TGA.*

*"It is an unfortunate setback for Australian ACS patients who would benefit from the device and we will continue to make the case for them as we seek to find an approval pathway with the TGA.*

*"We will continue commercialisation in Singapore and Malaysia where we have regulatory approval, and to progress regulatory approval processes in Japan, Hong Kong, Thailand, and Indonesia.*

*"While the Australian launch of the Guardian remains a key objective, Australia is only one of the eight countries in which Hydrix has exclusive rights, and these other markets with a combined population greater in size than the USA, represent a significant opportunity to focus on.*

*"Hydrix has multiple business segments. Pleasingly, Services returned to profitability in the first half on strong growth and the Venture companies are progressing to major inflection points which have the potential to materially increase the value of those investments in the year ahead."*

**-ENDS-**

**Authorisation:** This announcement has been authorised for release by the Board of Hydrix.

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**About Hydrix Limited**

Hydrix Limited (ASX: HYD) is a powerful product innovation company. Hydrix's purpose is to enhance the health, safety, and well-being of a billion lives. The company leverages its powerful product innovation capability across three business segments: Services: design, engineer and deliver world first products and innovation; Ventures: invest in high potential medtech clients; and Medical: distribute disruptive cardiovascular products.