

Hydrix receives regulatory approval to market and distribute The Guardian cardiac monitor in Singapore

Highlights

- The Guardian is now approved to be marketed and distributed in Singapore by Hydrix Medical
- This is the 4th country device approval for the Guardian in 13 months (Australia pending)
- There are approximately 30,000 acute coronary syndrome events each year in Singapore

Hydrix Limited (ASX: HYD) (Hydrix) is pleased to announce that the Health Services Authority of Singapore (HSA) has approved The Guardian to be marketed and distributed in Singapore by Hydrix Medical. HSA is the Singaporean Government's body responsible for regulating the importation, manufacture, export, and supply of medical devices.

Regulatory Approval Status

In Australia, Hydrix applied to the Therapeutic Goods Administration (TGA) for approval of The Guardian in July 2021 after US FDA approval in June 2021. While TGA approval is pending, and to support market adoption in Australia, Hydrix, in conjunction with a leading cardiology group, is finalising preparations for initial implants under TGA special access arrangements. These implants will be recorded in a clinical trial registry to collate and track Australian patient data after device implant.

Regulatory Application Status for The Guardian medical device

Country* / Agency	Hydrix Application Date	Status	Rights Owner
USA / FDA	Not applicable	Approved	Angel Medical Systems
Australia / TGA	26 July 2021	<i>Pending</i>	Hydrix under licence
Singapore / HSA	16 August 2021	Approved	Hydrix under licence
New Zealand / MMDSA **	11 August 2021	Approved	Hydrix under licence
Malaysia / Ministry of Health	27 December 2021	Approved	Hydrix under licence
Thailand / Thai Food & Drug Administration	12 October 2021	<i>Pending</i>	Hydrix under licence

* Regulatory pathway applications are planned for Japan, Hong Kong, and Indonesia

** Medicines and Medical Devices Safety Authority (MMDSA)

Singapore Market Readiness

The Guardian has been available in Singapore under special access arrangements (GN27) applied for by individual surgeons. To date, Dr Leslie Lam, a Cardiologist practising at The Farrer Cardiac Centre in Singapore, has successfully performed eight implants commencing August 2020, including one Malaysian domiciled patient who travelled to Singapore for the implant.

The value of the Guardian's continuous monitoring and alert function as an adjunct to current practices for managing cardiovascular disease is clearly demonstrated. Several of the eight implanted Singaporean patients have received alerts, including in one patient a "**see doctor**" diagnostic alert, leading to proactive cardiologist intervention of emerging cardiac issues resulting in life-improving changes to their medication.

Ms Vickie Edwards, Director of Sales & Operations for Hydrix Medical, commented:

"We are thrilled to receive market approval in Singapore. The approval is a key milestone achievement for Hydrix. The Guardian is now available to all suitable patients in Singapore, an important market.

This approval enables application for inclusion on the Table of Surgical Procedures (TOSP), a list of procedures for which MediSave / MediShield Life insurance reimbursement can be claimed. Until inclusion on the TOSP, patients can undertake the operation at their own cost."

The Guardian - Hydrix initial target market opportunity

There are an estimated 123,000 acute coronary syndrome incidences each year in Hydrix initial target markets. Approximately 25% may be deemed high risk patients and suitable for a Guardian implant.

- When the device received U.S. Food and Drug Authority (FDA) approval in June 2021, the FDA acknowledged it as a "first of kind" device that "satisfies an unmet need"
- The Guardian is an implantable continuous heart monitor with patient alerting capability for Acute Coronary Syndrome (ACS) events
- The Guardian can detect potential ACS events, including heart attacks, and alert the user to seek urgent medical attention even when a person has no symptoms or has atypical symptoms
- The surgical procedure for device implantation is similar to a typical single chamber pacemaker.

For illustration purposes, potential Hydrix revenue is \$24m to \$61m at a 2% to 5% ACS capture rate.

Potential Market Size (illustration only)			Est. Annual Unit Volume		Est. Annual Sales Value (A\$) ¹	
Region	Population (M)	ACS p.a.	2.0%	5.0%	2.0%	5.0%
Australia	25.8	75,000	1,500	3,750	\$15.0m	\$37.5m
Singapore	5.7	30,000	600	1,500	\$6.0m	\$15.0m
New Zealand	5.1	18,000	360	900	\$3.0m	\$9.0m
Direct to market	36.6	123,000	2,460	6,150	\$24.0m	\$61.5m

¹ Sales value estimates for illustration purposes only, units sales price target remains subject to health scheme price agreements for each jurisdiction on a direct to market model in Australia, Singapore & New Zealand.

For further information about Hydrix and the market opportunity for the Guardian, please refer to Hydrix's most recent [Company Overview](#).

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Authorisation: This announcement is authorised for release by the Board of Directors of Hydrix Limited.

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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 wellbeing of a billion lives. The company leverages its powerful product innovation capability across three complimentary commercial business segments. These segments are **Hydrix Services:** design and engineer products that transform markets; **Hydrix Ventures:** invest in high potential medtech clients; and **Hydrix Medical:** distribute disruptive cardiovascular products.