

ASX Announcement 21/07/2021

Hydrix Completes TGA Submission of the AngelMed Guardian System --- the World's only Implanted Heart Attack Alert System

Hydrix Limited (ASX: HYD, 'Hydrix' or the 'Company') today advises that following the recent US FDA PMA approval for commercial release in the USA of the AngelMed Guardian System (AMSG3-E), Hydrix has submitted its application to the Australian Therapeutic Goods Administration (TGA) for inclusion on the Australian Register of Therapeutic Goods (ARTG).

This application, which is being managed by the Hydrix Services Regulatory Team, cites the US FDA PMA approval, together with additional information specific to Australian requirements. Subject to due process, Hydrix anticipates approval to be forthcoming in the first half of calendar year 2022. Once the device is included on the ARTG, Hydrix can then market and sell the system commercially in Australia.

Paul Kelly, General Manager Hydrix Medical, today acknowledged the hard work of the Hydrix team and said, 'with each milestone achievement, we move one step closer towards commercialisation of the world's only implantable heart attack alert system'.

Hydrix also continues to work with the Medical Services Advisory Committee (MSAC) for approval for listing the procedure on the Medical Benefits Schedule (MBS), to provide a fee for the implanting physician, and Prostheses List Advisory Committee (PLAC) approval, to enable reimbursement of the AngelMed device under Private Health Insurance for policy holders.

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 purpose is to enhance the health, safety, and wellbeing of one Billion lives. The company leverages its powerful product innovation capability across multiple growth platforms: **Hydrix Services** design and engineer client products which transform industries; **Hydrix Ventures** generate equity returns through investing in high potential companies; and **Hydrix Medical** bring innovative medical technologies to market.