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Hydrix receives approval for Guardian device in Singapore

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Regulatory approval to market and distribute the Guardian cardiac monitor in Singapore



Australia's Hydrix Limited has announced 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.

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 afterdeviceimplant.

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.