

Hydrix welcomes first AngelMed Guardian device implant in the US

George Tchetvertakov October 1, 2020



The US FDA has approved AngelMed to re-implant 260 clinical trial patients under a continued access study.

Product innovation company [Hydrix \(ASX: HYD\)](#) received a welcome operational boost yesterday after one of the devices it distributes was successfully implanted into a patient with a prior acute coronary syndrome.

Hydrix's partner and product manufacturer, Angel Medical Systems (AngelMed), told the market that a former ALERTS Study patient in the United States had received the first implant of the next-generation AngelMed Guardian system as part of the ALERTS continued access study.

The cardiac monitoring device was implanted at the Pavilion Surgery Centre in California by Orange County Heart Institute and Research Centre electrophysiology director Kelly Tucker, MD.

Under the oversight of the US Food and Drug Administration (FDA), AngelMed has been approved to re-implant 260 clinical trial patients as part of a rolling study of patients with coronary syndromes.

Importantly, Angel Medical Systems invested more than \$240 million to develop its Guardian device and fund clinical trials, which culminated with regulatory approval in 2018.

Today's news is significant for Hydrix given that its subsidiary, Hydrix Medical, is the exclusive distributor of the AngelMed Guardian in eight Asia Pacific countries including Australia, Japan and Singapore, where four patient implants of the device were [completed in August 2020](#).

However, the ASX-listed entity is not entitled to revenue generated from implants in the US or any other jurisdiction outside its existing distribution agreement.

In March this year, Hydrix penned an exclusive seven-year distribution agreement for the Asia Pacific region and is actively trying to widen both use and awareness of the new medical device.

In what Hydrix described as a "life-changing device", the AngelMed Guardian system is designed to track significant changes in the heart's electrical signal and then alert patients to seek medical attention.

The system is capable of detecting silent heart attacks while the objective of the ALERTS continued access study is to provide former ALERTS patients access to the device, in the hope of improving their health outcomes.

"The AngelMed Guardian represents a real game changer in the management of coronary artery disease," Dr Tucker said.

"This is the first-ever surveillance tool for patients with a prior coronary event and has the potential to save countless lives and bring peace of mind to thousands of families. It is a great honour to be involved in this amazing technology."

Tackling acute coronary syndromes

According to the American Heart Association, there are as many as 605,000 new heart attacks in the US every year with a further 200,000 recurring incidents making the problem worse.

Meanwhile, several published studies have shown that at least 25% of heart attacks are unrecognised or silent.

In a bid to provide a useful tool that can alleviate the issue, Hydrix is carrying out the role of cardiovascular technology promoter to deliver innovative technologies into the health industry.

Hydrix claims each device uses artificial intelligence and machine learning algorithms to continuously monitor patient heart signals to warn of acute coronary syndrome events such as heart attacks.

Implanted like a single-chamber pacemaker, the AngelMed device is designed to forewarn of an impending acute coronary syndrome event caused by a partial or complete blockage of blood flow and oxygen to the heart, including episodes when there are no recognisable symptoms.

A vibrational alert, sound, and flashing LED light from a separate device combine to create the alarm, thereby prompting the patient to seek immediate medical help.

"This is a significant step forward in the progress of the AngelMed Guardian's commercialisation. We congratulate the team involved and look forward to ongoing positive news," Hydrix Medical general manager Paul Kelly said.

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