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Allied applies for heart patch approval in US

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Singapore: Allied Healthcare has lodged its Premarket Notification 510(k) Submission for CardioCel in the US. The FDA 510(K) submission is a major step in Allied's strategy to gain marketing approval for CardioCel in the US.

CardioCel is a cardiovascular tissue patch used to repair heart deformities including repairing and reconstructing heart valves. CardioCel has unique properties making it suited for use by surgeons as a regenerative cardiac repair tissue, as well as delivering key benefits to patients as compared to existing surgical approaches.

"The US is the largest global market for regenerative medicine and this is therefore a key milestone for Allied. Our US opinion leaders are very supportive of our application and key centers are ready to use CardioCel when approved by the FDA," said Allied Healthcare Group MD, Mr Lee Rodne.

This 510(K) submission is part of a global strategy to gain marketing approval for CardioCel. The company is anticipating the initial approval in Europe with its CE Mark mid-2013. To date the company has received strong support from key opinion leaders due to the benefits the product offers both patient and surgeon and has already been authorised for early access via the Authorised Prescriber Scheme in Australia.

"This is a significant milestone for us. Gaining approval gives us commercial entry into markets, as well as offering patients and surgeons a superior product with key differences and advantages from products currently used.Ã?Â CardioCel's potential to prevent additional revision surgeries for patients later in life will also be of enormous benefit to the patient community," said Mr Rodne.