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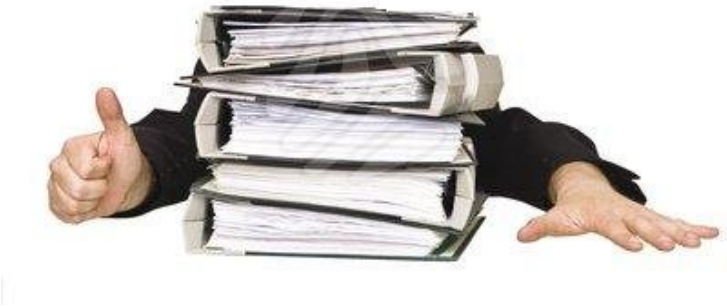
Conditional approval for Sunshine Heart device

01 October 2012 | News | By BioSpectrum Bureau

Conditional approval for Sunshine Heart's next gen device



Singapore: US-headquartered Sunshine Heart, which has a subsidiary in Australia, has received conditional approval from the US Food and Drug Administration (FDA) for its next generation C-Pulse System driver. This new iteration is designed to provide moderate to severe heart failure patients with enhanced patient comfort and performance. The new driver features a single unit which is lighter, quieter and approximately half the size of its predecessor and also features a number of software enhancements.

Conditional approval from the FDA allows the company to use this next generation driver for investigational purposes in the US at all sites that are currently enrolled in Sunshine Heart's North American feasibility trial. Sunshine Heart plans to provide the C-Pulse driver to all patients currently on its C-Pulse device at all US sites upon Institutional Review Board (IRB) approval. This second generation driver is also expected to be used in the company's future US pivotal trial once the FDA has approved its investigational device exemption, or IDE, as well as in Europe.

On June 7, 2012, the company announced that it received Health Canada's approval to use its next generation driver in its Canadian study at Royal Victoria Hospital. The company has also been granted Health Canada approval to expand the number of participants in the trial to 20 patients. All new patients enrolled in the trial and future trials will receive this next generation C-Pulse driver.

Sunshine Heart is an early-stage global medical device company committed to the commercialization of the C-Pulse Heart Assist System, an implantable, non-blood contacting, heart assist therapy for the treatment of moderate to severe heart failure.