March 30, 2021

Medtronic builds on its pulmonary legacy

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The US transcatheter aortic valve market is pretty much locked in place, with Edwards Lifesciences and Medtronic having 65% and 35% share respectively. Consequently, the battle is moving into the mitral and tricuspid valves – but also back into pulmonary. Medtronic's Melody pulmonary prosthesis was the first transcatheter heart valve of any kind to reach market anywhere in the world, having been CE marked in October 2006 and approved in the US under a humanitarian device exemption in 2010. Last week Medtronic added a second pulmonary valve, Harmony, to its US offering. Harmony can be used in patients with severe pulmonary regurgitation – those with a faulty native or surgically implanted valve that does not close properly, allowing blood to flow from the pulmonary artery back into the heart. This is a slightly different indication from Melody's; the older product is intended for patients with moderate pulmonary regurgitation and/or stenosis, a narrowing of the valve. In its pivotal trial the 70 patients who received Harmony remained alive at 30 days, and of the patients who underwent echocardiography 89.2% had acceptable haemodynamics at six months. The FDA must have been impressed: approval came in 4.6 months, the fastest decision for a pulmonary valve yet.

US approvals for transcatheter pulmonary valves

Device	Company	Filing type	Decision date	Review time (mths)
Melody	Medtronic	HDE	Jan 25, 2010	16.9
Melody	Medtronic	PMA	Jan 27, 2015	5.2
Sapien 3	Edwards Lifesciences	PMA	Aug 31, 2020	5.7
Harmony	Medtronic	PMA	Mar 26, 2021	4.2

Source: Evaluate MedTech & US FDA.