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Therapeutic focus – Another heart valve for Europe but US market remains limited

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Medtronic's CoreValve Evolut R, CE-marked last week, is the latest catheter-delivered artificial heart valve to reach the now crowded European arena. But the slower pace of approvals at the US FDA means that only five are available in the US, and this larger market is contested by just two companies.

With this in mind it is worth examining the more recent entrants to the European space (see table below). As well as the two leaders, Medtronic and Edwards Lifesciences, smaller companies including three private firms have staked out a claim. At this point in the segment, incremental innovations are crucial to give each successive new valve an edge over the previous technologies. The US market could soon open up to a much wider range of offerings.

That is not to say that the smaller companies will still exist by the time their valves get to the US – if, indeed, they do. Without large marketing operations it is difficult for these groups to carve a niche against the leaders, though many are building banks of clinical evidence aiming to prove their utility in particular populations.

Transcatheter valves in the US: first-time PMAs

Company	Device name	Type of valve	Date of EU approval (CE mark)	Date of US approval	Number
Medtronic	Melody	Pulmonary	October 3, 2006	January 25, 2010	H080002*
Edwards Lifesciences	Sapien (transfemoral)	Aortic	September 30, 2007	November 2, 2011	P100041
Edwards Lifesciences	Sapien (transapical)	Aortic	December 6, 2007	October 19, 2012	P110021
Medtronic	CoreValve	Aortic	May 16, 2007	January 17, 2014	P130021
Edwards Lifesciences	Sapien XT	Aortic	March 2, 2010	June 16, 2014	P130009

**Human Device Exemption approval*

It is more than possible that instead, the smaller players started on this route with their eyes on the usual prize: a takeout by one of the larger firms keen to add a new innovation to their valve franchises. Certainly JenaValve considers this a sensible outcome (*EP Vantage interview – JenaValve aims to triple sales or sell itself, June 25, 2013*).

Direct Flow Medical, whose first valve was CE marked in early 2013, is pursuing a US approval trial called Salus but this will not yield results until the second half of 2016. Until then, it is moving to spur uptake in Europe by shoring up its clinical evidence. Data released last week at the ESC meeting in Barcelona showed that the valve was as successful in a real-world population as it was in the more strictly defined population enrolled in the CE mark approval trial.

The company will be hoping that these data spur cardiologists to use the valve in older, sicker patients, thereby upping sales.

The third private company with a CE-marked valve, France's Symetis, is at roughly the same point as JenaValve: both gained CE mark – on the very same day – for transapically delivered aortic valves, and both are developing transfemoral versions. Symetis says it expects the transfemoral valve to make its European debut this year.

With more than 20 valves available in Europe – naturally, all those approved in the US had already gained CE

mark – companies are jockeying for market share by employing new technologies. CoreValve Evolut R is recapturable, allowing the doctor to have a second try if the valve is initially deployed in the wrong position.

But many other devices have this ability, including Boston Scientific's Lotus and Edwards' Sapien 3. At this point, in Europe at least, it is all about tweaking older tech to stay competitive.

The US landscape is unlikely to change significantly for some time to come. The average lag between European and US approval for the five products that have made it to both markets is 4.6 years. And while all three of the private companies are making moves towards US approval, they are surely outgunned when it comes to marketing power. In any case, a third company is unlikely to enter the US before 2016.

Both the EU and the US markets are now and will continue to be dominated by Edwards and Medtronic. But it will be a long time before US cardiologists – and their patients – have the same breadth of choice as their European counterparts.

Mind the gap: selected transcatheter valves approved in the EU, but not the US

Company	Device name	Valve	Date of EU approval (CE mark)
Edwards Lifesciences	Sapien Pulmonic	Pulmonary	May 26, 2010
Medtronic	CoreValve (transfemoral approach)	Aortic	September 7, 2010
Medtronic	CoreValve (subclavian approach)	Aortic	December 9, 2010
Medtronic	CoreValve 31mm	Aortic	August 18, 2011
JenaValve Technology	JenaValve	Aortic	September 30, 2011
Symetis	Acurate TA	Aortic	September 30, 2011
Medtronic	CoreValve (direct aortic approach)	Aortic	November 7, 2011
Medtronic	CoreValve Evolut	Aortic	September 26, 2012
St. Jude Medical	Portico (23mm size)	Aortic	November 19, 2012
Direct Flow Medical	Direct Flow Medical 25mm and 27mm Transcatheter Aortic Valves	Aortic	January 28, 2013
Boston Scientific	Lotus	Aortic	October 28, 2013
St. Jude Medical	Portico (25mm size)	Aortic	December 12, 2013
Direct Flow Medical	Direct Flow Medical 29mm Transcatheter Aortic Valve	Aortic	January 9, 2014
Edwards Lifesciences	Sapien 3	Aortic	January 27, 2014
Direct Flow Medical	Direct Flow Medical 23mm Transcatheter Aortic Valve	Aortic	August 21, 2014
Medtronic	CoreValve Evolut R	Aortic	September 3, 2014

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