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Event – Ortho panel delay a disappointment for VertiFlex

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The last-minute postponement of an FDA panel meeting evaluating VertiFlex's spinal graft is not a crisis for the company, but neither is it good news. The new date in February means a delay of more than two months before the company can launch the product in the US.

The Superion graft is crucial to VertiFlex, not least because the group sold many of its non-core products to Stryker last year. VertiFlex has not raised money since 2011, and surely wishes to see sales as soon as possible. And with FDA approval often a trigger for an acquisition, the private company's backers may well be feeling frustrated.

Good enough?

Superion, an interspinous spacer for treating lumbar spinal stenosis, has been CE marked since 2007, so the lag between reaching Europe and the US approval is even more pronounced than usual. The device can be implanted via a minimally invasive procedure at one or two adjacent levels, where it helps relieve pain and cramping in the back and legs.

And it appears to do so effectively. Whether it is any better than devices already available, however, is open to debate. In the pivotal US trial, called Isiss, Superion's ability to decrease pain and improve function was compared with that of Medtronic's X-Stop, which is already marketed in the US.

Isiss enrolled 470 patients with moderate lumbar spinal stenosis who did not respond to conservative care, randomised 1:1 to Superion or the control arm. Results from the first 250 patients indicate that there is little difference between the two products, as the table below shows.

Isiss – Superion's pivotal trial data						
	Axial pain (mm)		Extremity pain (mm)		Back function (%)	
	Baseline	At 2 years	Baseline	At 2 years	Baseline	At 2 years
Superion	59 ± 26	21 ± 26	67 ± 24	14 ± 22	37 ± 12	18 ± 16
X-Stop	55 ± 26	21 ± 25	63 ± 24	18 ± 23	39 ± 12	20 ± 16

All the decreases in pain and the improvement in back function were statistically significant, with p values of less than 0.001.

Scores on the Zurich Claudication Questionnaire, assessing symptom severity and physical function, and patient satisfaction scores were also very similar with the two devices. At two years, 16% of Superion patients required a second operation, compared with 17% of X-Stop recipients.

Wait

The full data on all 470 Isiss patients will now come under scrutiny on February 20, when the Orthopaedic and Rehabilitation Devices Panel will finally meet. They are quite possibly good enough to secure premarket approval – after all, they show Superion to be very similar to Medtronic's approved graft.

It is when the product reaches market – if the FDA grants it permission – that these trial results could fall short. Perhaps VertiFlex intends to compete on price; hospitals are always open to that approach. But Medtronic has the heft and product range to attract large hospital contracts that could make it tricky for VertiFlex to enter.

The obvious solution to this problem is a takeover. But as no potential buyer has yet emerged, any companies considering acquiring VertiFlex will surely wait until the outcome of the adcom, if not the approval decision itself.

Study	Trial ID
Isiss	NCT00692276

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