Evaluate Vantage

June 22, 2018

Tandem comes out the winner of the diabetes device approvals

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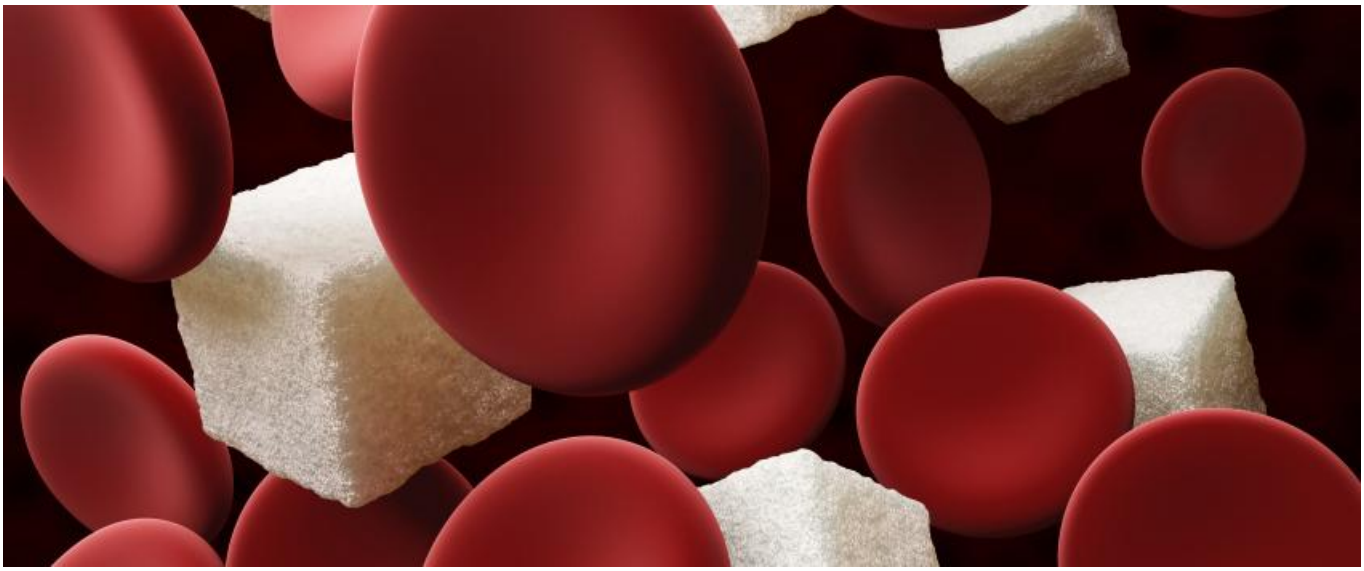

Battle of the algorithms.

The implantable continuous glucose monitor developed by Senseonics was granted US premarket approval yesterday, and Medtronic's Minimed 670G, a rudimentary artificial pancreas, was approved in a wider patient population. But the real winner, at least in terms of share performance, is Tandem Diabetes Care.

Tandem won FDA approval for a component of an artificial pancreas of its own. The company's t:slim X2 insulin pump got the go-ahead yesterday, and when used along with the Dexcom G6 glucose monitor the technology is as good as or perhaps even better than Medtronic's system. Tandem's shares are up 25% in early trading.

Tandem's new product incorporates an algorithm called Basal-IQ, which suspends insulin delivery half an hour before the point at which the patient's blood glucose is predicted to drop below 80mg/dL, or if glucose is currently below 70mg/dL and falling. Insulin delivery resumes once glucose values start to rise.

This type of feature is called predictive low glucose suspend. Medtronic introduced this kind of tech with the 670G, which was approved in the US in September 2016. But the Tandem-Dexcom combo has an edge over Medtronic's device in that the G6 is one of two continuous glucose monitors – the other is Abbott's FreeStyle Libre – to be approved without the requirement for fingerstick calibration (*Dexcom clearance blazes a trail, March 28, 2018*).

Young and old

The t:slim X2 is the first automatic insulin delivery system approved for use by children six years old and up, Tandem says. But the label for Medtronic's 670G system – which comprises both sensor and pump – was yesterday extended to allow the product's use in patients aged seven and older. It had previously been greenlit for 14-year-olds and up. Given that the main market for artificial pancreases is type 1 diabetes, the form that tends to start when a patient is young, the paediatric market is a crucial one.

By contrast Senseonics' implanted glucose meter, Eversense, is only approved for adults. The approval was all but a formality after an FDA panel voted unanimously in favour of its safety, efficacy and risk-benefit ratio in March, despite the fact that Eversense bears little resemblance to current CGMs (*Event – FDA panel to make sense of implanted glucose meter, March 13, 2018*).

It is probably only a matter of time before Eversense is incorporated into a viable artificial pancreas-type system too – indeed one such collaboration, with pump maker Beta Bionics, is in the very early stages. For

now, though, Tandem and Dexcom seem to be leading the field.

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