Evaluate Vantage

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US medtech approvals dip, but could pick up in 2017

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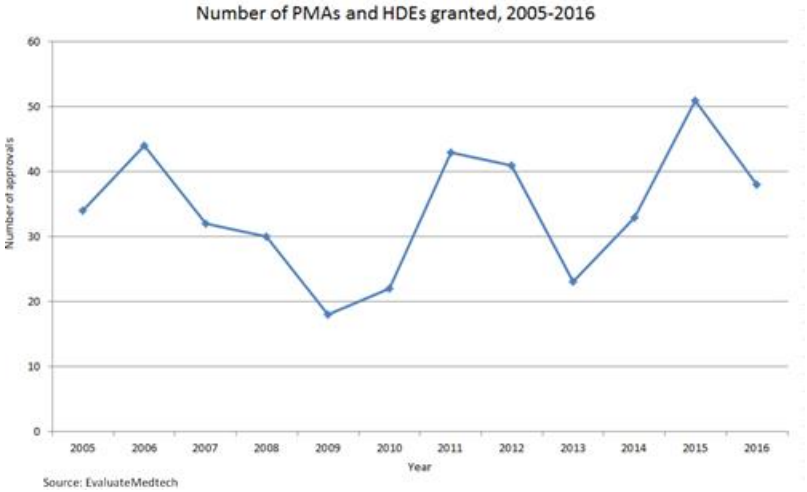
Fewer approvals that are slower to arrive – not what the medical device industry had wanted to see from the US FDA. Just 38 first-time premarket approvals were granted to innovative devices last year, down 25% from the 51 awarded the year before (see graph below). And the agency has taken slightly longer, on average, to grant those approvals – 18.1 months compared with 17.3 months in 2015.

The coming year could be very different. The 21st Century Cures Act came into force at the end of last year, and contains provisions that would relax approval criteria for medical devices. And with the current US administration dropping hints that the requirements for device approval could be loosened further still, the years to come might see higher numbers and faster decisions.



There will always be some variation in the number of devices that gain PMAs, whatever policies the FDA puts in place. And it is true that, until the 21st Century Cures Act became law the FDA was inclining toward becoming more liberal.

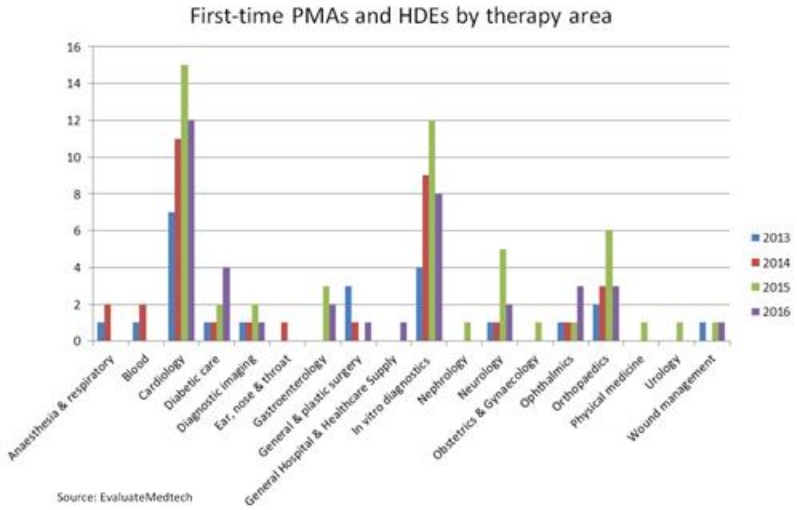
One of the factors contributing to the smaller number of approvals in 2016 might have been the ongoing, and worsening, venture crisis. There are hints that larger medtech groups are finally discovering that the pool of start-ups through whose acquisition they can obtain innovative technologies has appreciably shrunk thanks to the lack of early funding available.

This so-called “innovation crunch” may now be starting to manifest itself in the approval numbers.

No HDEs

Notably, there were no humanitarian device exemption approvals in 2016. This type of approval may be granted to devices that treat conditions that affect fewer than 4,000 people a year, and permits a slightly lower burden of proof of efficacy. Six such approvals were granted in 2015, and four the year before that.

Again, this is likely to change in 2017. One of the provisions of the 21st Century Cures Act is to expand the number of patients an HDE-approved device can treat to 8,000 per year, allowing many more devices to qualify for this pathway. The HDE review process will also be sped up.



The decline in the number of approvals is even more apparent when the figure is broken down by therapy area. The green bars, signifying 2015's approvals, are clearly the largest, with the purple bars for 2016 showing a decline in the number of approvals in ten areas, against an increase in only four.

As usual, the cardiology space has seen the most new products approved, and at the swift pace of 13.3 months on average. This is despite the average being dragged down by the Amplatzer PFO Occluder developed by St. Jude Medical, which the FDA approved nearly four years after its resubmission (*Heart plug approval a minor win for St. Jude, October 31, 2016*).

The fastest approval overall in 2016 was that of Medtronic's Minimed 670G system, a combination of a blood sugar sensor and an insulin pump which is the closest device yet to an artificial pancreas (*Medtronic's artificial pancreas leads the field, September 29, 2016*). Perhaps aware of the great demand for and excitement around this technology, the FDA waved it through in just 3.4 months.

Average review times of first-time PMAs and HDEs by therapy area (months)				
EvaluateMedTech Device Classification - L1	**2013**	**2014**	**2015**	**2016**
Anaesthesia & respiratory	61.3	18.5	-	-
Blood	13.2	8.7	-	-
Cardiology	17.1	12.9	14.4	13.3
Diabetic care	15.7	19.0	9.8	12.0
Diagnostic imaging	16.8	13.0	11.7	11.6
Ear, nose & throat	-	9.5	-	-
Gastroenterology	-	-	17.7	9.6
General & plastic surgery	68.2	28.7	-	24.0
General hospital & healthcare supply	-	-	-	39.8
In vitro diagnostics	8.6	13.3	11.3	11.1
Nephrology	-	-	25.1	-
Neurology	40.5	8.9	19.4	10.6
Obstetrics & gynaecology	-	-	12.9	-
Ophthalmics	21.4	11.0	28.1	9.6
Orthopaedics	30.0	48.0	24.5	37.8
Physical medicine	-	-	80.9	-
Urology	-	-	29.3	-
Wound management	31.2	-	14.7	11.5
Average	26.9	16.7	17.3	18.1

A look at the other pathway used by innovative devices is reassuring. De novo 510(k) clearances are granted to low-risk devices that are unlike anything previously available. 24 devices obtained de novo clearance last year, up from 18 in 2015.

As there is generally less data to assess, these clearances take less time than PMAs, with the average time to approval for de novos coming in at 13.4 months. The FDA has simplified the application process in recent years, and this has surely played a part here. Still, it is slower than 2015, when de novos were greenlit in an average of 10.9 months.

De novo clearances by year		
Year	**Number**	**Ave time (months)**
2007	7	4.5
2008	3	6.0
2009	4	12.4
2010	3	14.4
2011	10	12.9
2012	10	15.3
2013	18	9.9
2014	28	13.7
2015	18	10.9
2016	24	13.4

2016 has been a disappointing year compared with the heights of 2015, though still broadly within the range of recent years. It will be up to the FDA's new commissioner, whoever it may be, to reverse the decline in both number and speed of approvals without, more importantly, compromising patient safety.

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