Evaluate Vantage

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A quiet six months for device approvals

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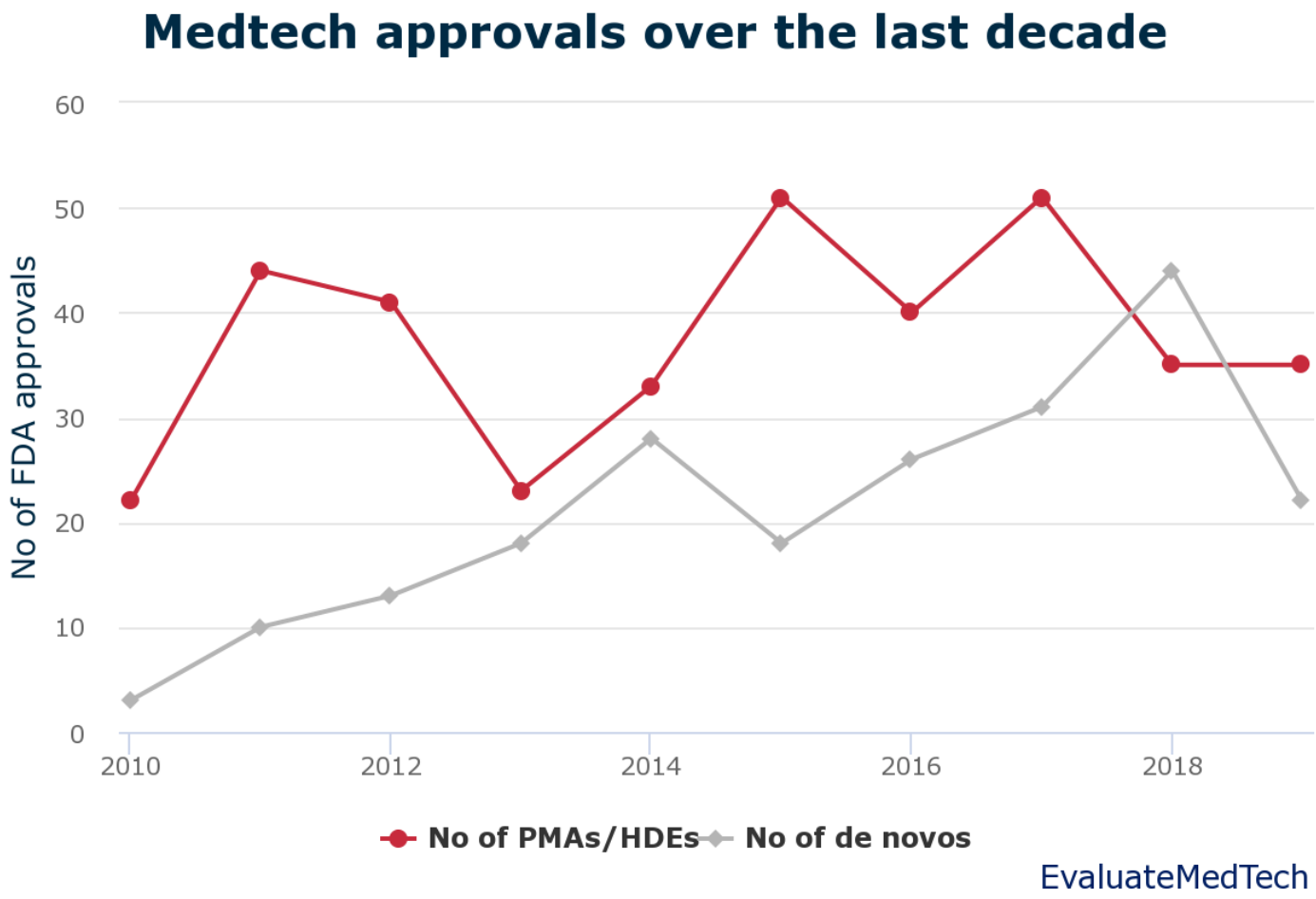
The second half of 2019 saw half as many innovative medical devices approved as the first.

Increased scrutiny of high risk devices following several well-publicised cases of patient harm could be one possible reason behind the sharp drop in the rate of FDA approvals of these types of product in the second half of 2019, as opposed to the first. But this does not explain the equally precipitous fall in low-risk device clearances, a marked contrast to the figures in 2018.

At the half-year point, 23 innovative high-risk devices had been approved, but the second half of last year saw only 12 premarket approvals and humanitarian device exemptions – the regulatory paths taken by high-risk medical technologies. At 35, across all of 2019 the total approvals for this class of device was the same as in 2018.



There are several factors that might have acted as brakes on the agency's activity. The most obvious was the furore surrounding the Implant Files investigation in November 2018. This highlighted several cases of neglectfully designed and manufactured medical devices, including pacemakers, contraceptive implants and surgical meshes.

This might have prompted the agency to be more circumspect when considering whether to approve high-risk products or companies more cautious in submitting approval requests. The timing is probably about right. As the table below shows, devices take an average of a year to win their PMA or HDE, so those approved in the second half of 2019 would just have begun the review process when the Implant Files broke.

Another could be the departure of commissioner Scott Gottlieb at the end of March; Mr Gottlieb had presided over a boom in device approvals in 2018 and this might have faltered without his oversight.

2019's PMAs and HDEs by therapy area		
EvaluateMedTech classification	**No of PMAs & HDEs**	**Average approval time (mths)**
Cardiology	12	13.0
In vitro diagnostics	7	7.2
Orthopaedics	7	18.2
Neurology	3	10.8
Urology	2	8.7
Ear, nose & throat	1	5.9
Obstetrics & gynaecology	1	7.5
Gastroenterology	1	9.2
Anaesthesia & respiratory	1	11.5
Overall	**35**	**12.0**

The big drop in de novo clearances is harder to explain. Firstly, most implanted devices cannot use this pathway so the Implant Files could only have had a minimal effect.

There was also a programme at play that ought to have made the de novo pathway more, not less, popular. At the end of 2018 the FDA said it was considering rejigging the 510(k) clearance pathway to force companies to use more recent predicates in their submissions (*The FDA's proposed changes to device regulation are thin on detail, December 11, 2018*). The agency said at the time that it expected these proposals to prompt more de novo applications, since these do not require predicates at all.

2019's de novos by therapy area		
EvaluateMedTech classification	**Number of de novos**	**Average approval time (mths)**
In vitro diagnostics	7	9.8
Neurology	5	10.5
Gastroenterology	2	8.4
Diabetic care	2	4.3
Anaesthesia & Respiratory	1	18.8
Wound Management	1	13.2
Orthopaedics	1	12.5
Endoscopy	1	12.0
Blood	1	11.3
Cardiology	1	10.3
Overall	**22**	**10.2**

A silver lining to this data is that though there are fewer approvals, those that have been granted came through relatively swiftly. Last year the FDA took an average of 15 months to approve high-risk novel products and 13 months for low-risk; both of these figures have fallen.

The safety of patients ought not to be compromised, of course, and medical technologies must be subject to thorough reviews. But device makers will be disappointed by the US regulator's performance in the second half of 2019.

There is always a certain amount of fluctuation in the number of devices submitted to the FDA each year, so some of the downturn could be due to chance. But a number of larger medtechs, Medtronic among them, are aiming to bring a suite of new products to market in 2020, so next year's figures could be very different.