Evaluate Vantage

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FDA keeps the new devices coming

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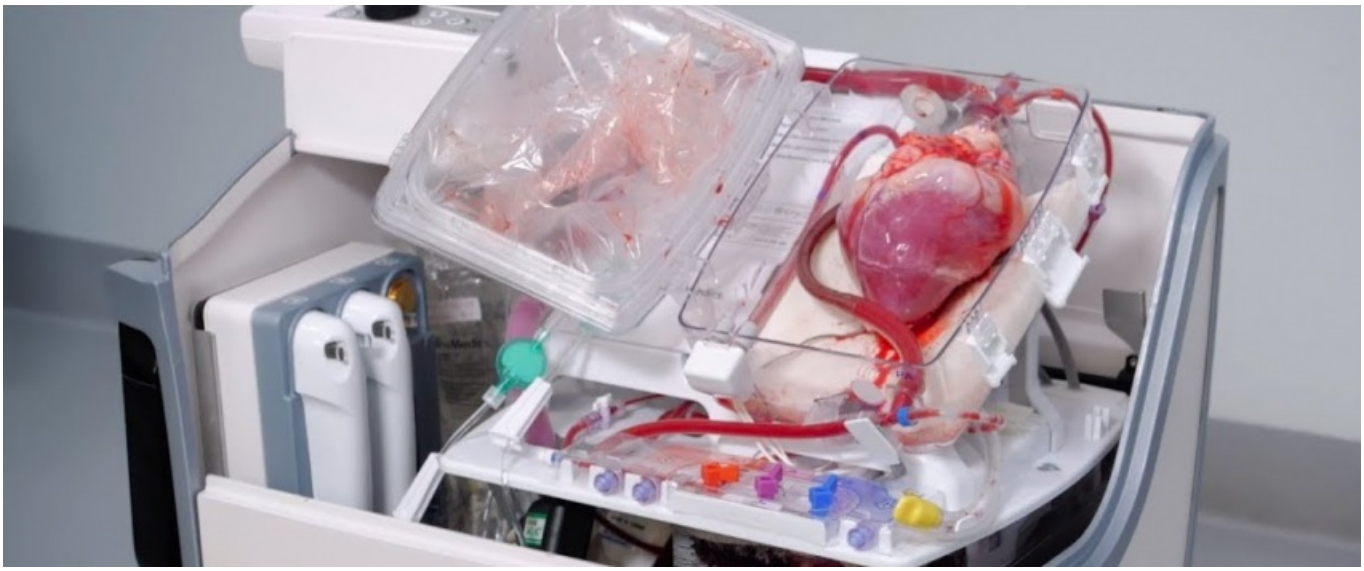
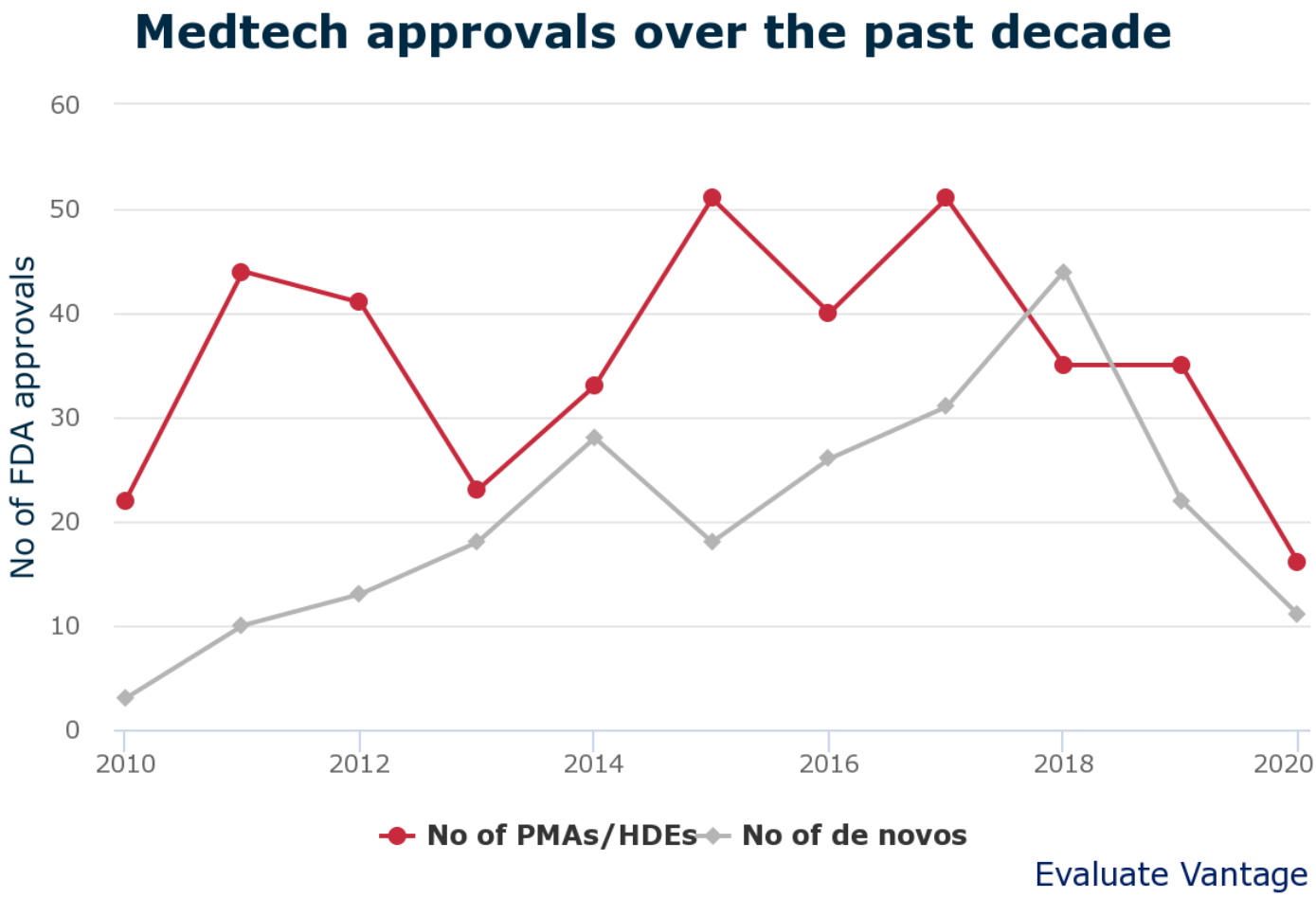


The pandemic prompts only a slight drop in medtech approvals.

As the FDA grapples with a once-in-a-generation crisis and tries to speed drugs, vaccines, devices and diagnostics to market, the less pressing business of evaluating and approving non-Covid-19-related medical technologies has taken a back seat. Even so, the number of devices approved by the agency has not dipped as much as might have been feared.

In the first half of 2020 the FDA approved 16 high-risk and 11 low-risk novel medical devices, putting it only slightly behind its performance last year. As importantly, the speed at which these products made it through the regulatory process has barely slowed. Still, last year saw a slowdown in the second half, so medtechs must hope that the FDA is able to keep up the pace in the coming months.



In vitro diagnostics make up the majority of the products granted premarket approval by the FDA – the type of approval used for products intended to be used in supporting or sustaining human life or preventing impairment of health. Many of these high-risk diagnostics are for viral infections, including hepatitis B and C, HIV and human papillomavirus.

Absent from this analysis is any diagnostic for Covid-19 infection or test for immune response. The FDA has not granted approval or clearance for any such test – instead these are afforded regulatory oversight in the shape of emergency use authorisation, a less rigorous stopgap measure for a time of crisis. By the end of last week more than 120 Covid-19 test had been authorised for use in the US (*Healthineers' Covid-19 antibody test wins out in the UK, July 13, 2020*).

Average review times of first-time PMAs and HDEs by therapy area (months)		
EvaluateMedTech classification	**H1 2020**	**H1 2020**
Cardiology	4	21.0
In vitro diagnostics	9	10.8
Neurology	1	9.6
Ophthalmics	1	5.9
Urology	1	30.0
Total	**16**	**-**
Average		**14.2**
Source: FDA.		

Perhaps because of its determination to keep new technologies flowing, the agency has taken a fairly lenient stance on at least some of these approvals. The FDA granted a PMA for the ReActiv8 neurostimulator, developed by Mainstay Medical, despite the device having failed its pivotal trial.

Unusually for a neurostimulator trial in back pain, the Reactiv8-B study included a sham control arm. This was its undoing, with an unexpectedly high response rate among the sham patients (*Neurostimulation sham*

sculpters Mainstay, November 19, 2018). The FDA was persuaded to approve anyway – despite the availability of other forms of neurostimulation for back pain – awarding the approval after less than 10 months.

Another potential worry, in terms of both sufficiently stringent oversight of new devices and maintaining a decent number of approvals by year-end, is the postponement of FDA advisory committee meetings. Adcoms scheduled to assess PMAs for Transmedics' ex-vivo heart perfusion and monitoring system and Refocus Group's VisAbility Micro Insert, an eye implant intended to improve near vision in presbyopic patients, have been postponed without new dates being announced.

Average review times of de novo 510(k)s by therapy area (months)		
EvaluateMedTech classification	**H1 2020**	**H1 2020**
Cardiology	1	5.9
Diagnostic imaging	1	5.4
Endoscopy	1	9.3
Healthcare IT	1	2.0
In vitro diagnostics	3	10.5
Nephrology	1	18.7
Ophthalmics	1	11.6
Orthopaedics	1	16.6
Urology	1	10.8
Total	**11**	
Average		**10.2**
Source: FDA.		

The rate of de novo clearances – those granted to low-risk devices that are so innovative that no previously approved device can stand as a predicate – is tracking at exactly the same pace as last year. The first six months of 2020 saw 11 de novos granted in an average of 10.2 months, compared with 22 across all of 2019, in the same average time.

It is reassuring that the FDA is still attending to its routine work even as it is under political pressure to rush Covid-19 diagnostics and therapeutic devices on to the US market. Ventilators, for example, are also eligible for emergency use authorisation. Provided it can continue to do so during the second half of the year, this is one area in which 2020 could come to be regarded as almost normal.