Evaluate Vantage

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The FDA takes its foot off the pedal

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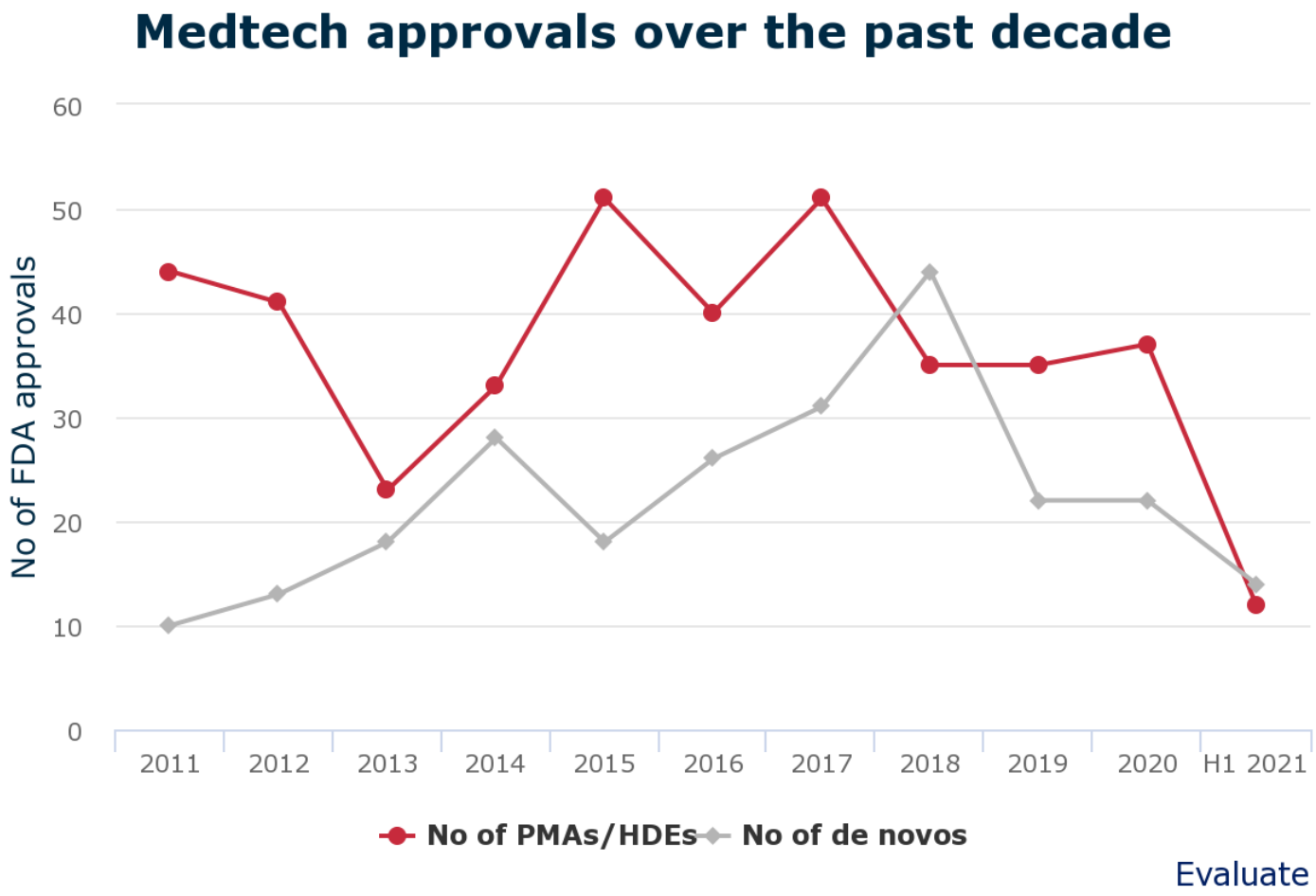
US approvals of high-risk medical devices are way down.

Last year the FDA kept up a scorching pace of medical device approvals in tandem with rushing Covid-19 diagnostics, and other devices necessary to aid with the pandemic, to market via emergency authorisations.

Now it seems that burnout might have hit the agency. During the first six months of 2021 the FDA awarded just 12 first-time premarket approvals and one humanitarian device exemption. If this rate is maintained throughout the second half this year will see the fewest high-risk devices reach the US market since 2013.

A different trend is apparent when it comes to low-risk novel devices. With 14 de novo 510(k) clearances awarded in the first half of 2021 the full-year total could end up higher than that for 2020 or the year before.



In fairness, the agency had warned that a slowdown might be coming. In April Jeff Shuren and William Maisel of the FDA's Center for Devices and Radiological Health (CDRH) wrote that the unprecedented Covid-19-related workload has put a significant strain on the CDRH's resources, particularly within the office that deals with in vitro diagnostics submissions.

Mr Shuren and Mr Maisel added that there was a backlog of non-Covid-19 files pending review, and said that the CDRH expected delays in meeting review timelines for some of these submissions.

In fact, while fewer devices seem to be getting approved, the speed at which the agency is reviewing those that do get the nod is very respectable. The high-risk innovative devices, which must go through either the PMA or HDE routes, received approval in just over a year, on average, while the low-risk products were faster still.

H1 2021's approvals by therapy area				
Evaluate Medtech classification	**Number of PMAs/HDEs**	**Avg approval time (mths)**	**Number of de novos**	**Avg approval time (mths)**
Anaesthesia & respiratory	-	-	1	10.5
Cardiology	5	10.9	4	13.2
Ear, nose & throat	1	15.0	1	12.9
Gastroenterology	-	-	1	7.0
General & plastic surgery	-	-	1	22.4
In vitro diagnostics	3	16.7	1	9.9
Neurology	-	-	2	7.3
Ophthalmics	1	11.1	1	10.2
Orthopaedics	1	7.6	-	-
Physical medicine	-	-	2	10.2
Radiology	2	10.1	-	-
Total	13	-	14	-
Average	-	12.2	-	11.5
Source: Evaluate Medtech & FDA.				

The impact of Covid-19 can be seen in the types of product receiving approval. In previous periods, the most approvals have almost always gone to in vitro diagnostics – but not this time. Only four assays were given the agency's blessing, as the diagnostics wing of the regulator concentrated on evaluating Covid-19 tests via the emergency us authorisation pathway.

One of the few diagnostics approvals is particularly notable. The French firm Biomérieux obtained de novo clearance of its Biofire Respiratory Panel 2.1, which tests for a range of bacterial and viral pathogens including the virus that causes Covid-19 – the first time a Covid-19 test has received a formal approval, rather than an emergency authorisation.

Since this kind of authorisation lapses after the state of emergency in the US is lifted, the move shows Biomérieux is looking beyond the end of the pandemic. It is highly likely that other diagnostics groups will also seek clearance or approval for their Covid-19 tests.

The first half of 2021 saw both high and low-risk devices for cardiovascular applications outpace diagnostics in terms of the number of approvals. One of these was the quickest: Medtronic's transcatheter pulmonary valve, Harmony, got its PMA after just 4.2 months of review time – speedy work for an overburdened agency.