Evaluate Vantage

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Device approval times lengthen

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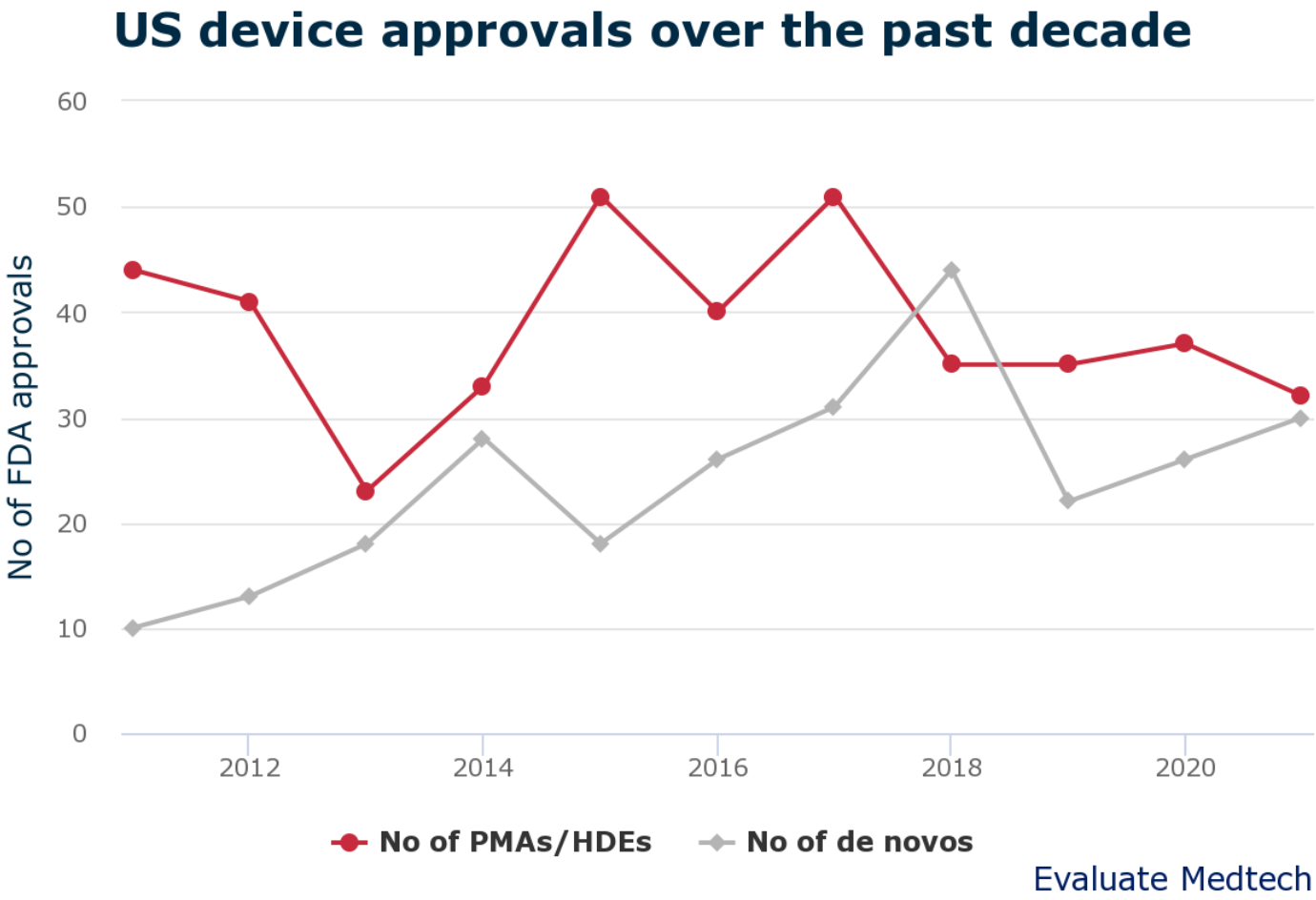
The agency takes its time – particularly with diagnostics.

With 32 high-risk innovative medical devices approved in 2021, the picture for companies trying to bring new products to the US market is not as bad as it appeared six months ago. By the end of the year, the overall number of approvals was only one shy of 2020's total.

In terms of review times, however, the agency has slowed down. Compared with 2020, it took around a month longer, on average, to examine the submissions for the approved devices. This is perhaps understandable: in a blog post towards the end of December, Jeff Shuren and William Maisel of the FDA's devices section said that a sustained high volume of filings was straining the centre's resources.

While the number of premarket approvals – the regulatory path that must be taken by high risk devices – fell slightly from 2020's total, this was balanced by a year-on-year increase in the number of low-risk products cleared for sale via the de novo clearance route.

This analysis considers first-time premarket approvals, humanitarian device exemptions and de novo 510(k) clearances. Standard 510(k)s and supplemental approvals are not covered.

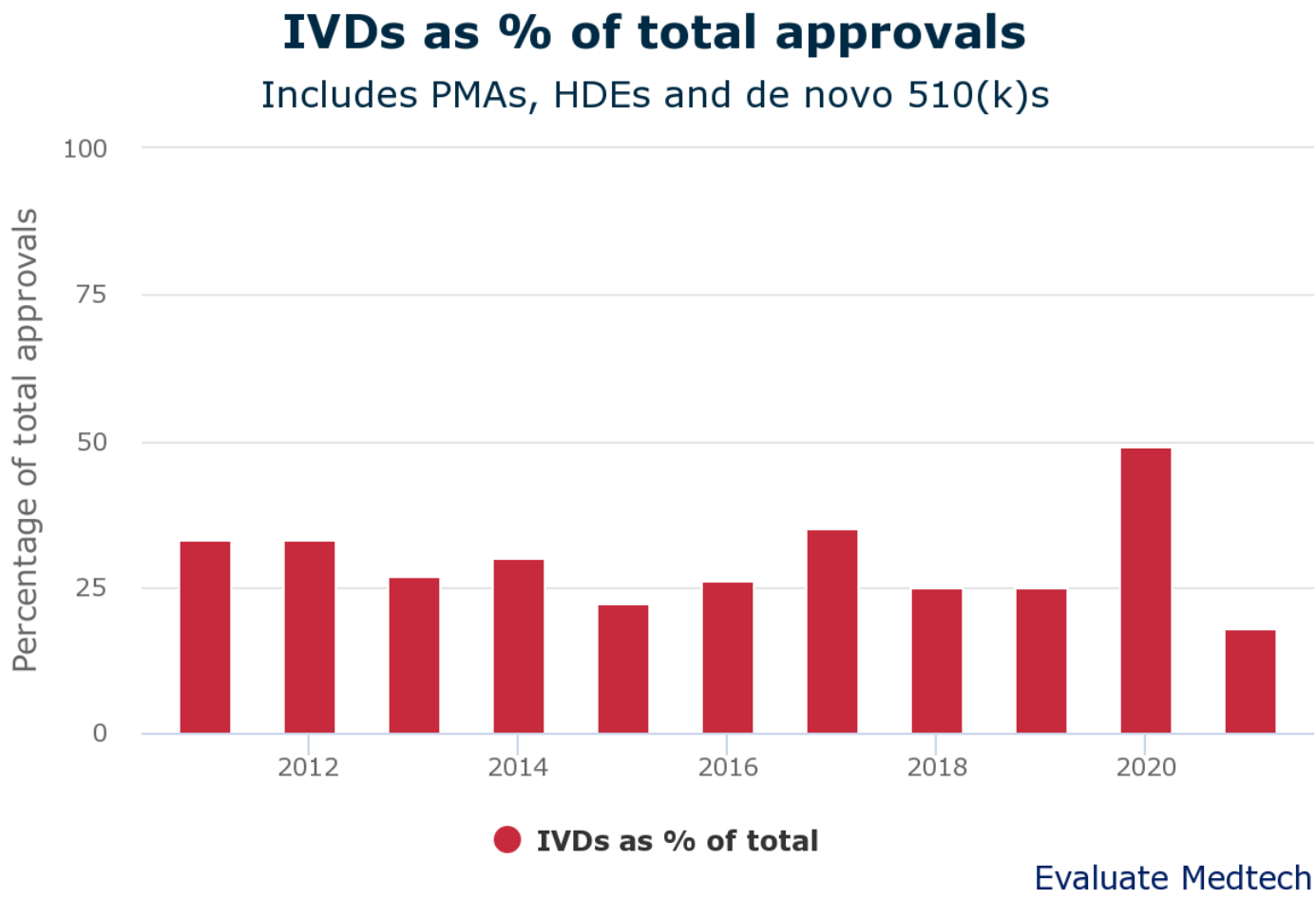


According to the FDA Voices blog post, the FDA's Center for Devices and Radiological Health has issued emergency use authorisation to over 1,900 medical devices for Covid, and continues to receive more than 100 EUA requests per month. On top of this the number of conventional submissions – PMAs and 510(k)s, including de novos, supplemental approvals, and pre-submissions – increased for the second consecutive year, reaching almost 18,000 last year.

With all this going on it is hardly surprising that the agency's timelines have slipped slightly. It should be stressed that the timings listed below are based solely on successful filings; the FDA does not make available the review times for rejected submissions.

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)**
Cardiology	13	14.0	6	12.5
Ear, nose & throat	1	15.0	2	17.2
Gastroenterology	3	20.5	1	7.0
In vitro diagnostics	8	15.1	3	11.5
Neurology	1	5.9	5	7.3
Ophthalmics	1	11.1	2	8.9
Orthopaedics	1	7.6	3	9.3
Radiology	2	10.1	1	17.6
Total	**32**		**30**	
Average		**13.9**		**11.2**
Note: table only shows areas with at least three approvals. Source: Evaluate Medtech, FDA.				

One notable feature of last year's approvals is the dearth of diagnostics. From 2011 to 2019, an average of 28% of approvals awarded by the FDA were for in vitro tests of one kind or another. In 2020, this ballooned to 49%, as tests for cancer and infectious disease were prioritised by the agency. This figure did not include Covid tests, since all those that reached the US in 2020 did so under emergency authorisation.



Last year, however, saw a sharp pullback, with just 11 assays approved or cleared – 18% of the total. This was an upshot of a deliberate strategy by the agency: in April it said it would decline IVD pre-submission requests unless they were related to a Covid test, a companion diagnostic, a breakthrough device designation request, or an assay that would have a significant public health impact.

This decision was reversed in June 2021, but the FDA said that timelines for non-Covid IVD filings would have to be extended. And sure enough, the IVD approval time was an average of more than 15 months last year, versus an average of 10.5 months for the prior decade.

The FDA says that it hopes to speed up again in the coming year. An easing of the pandemic, and thus of the Covid-related workload with which the agency is grappling, would surely help.