Evaluate Vantage

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Medtech approvals stagnate

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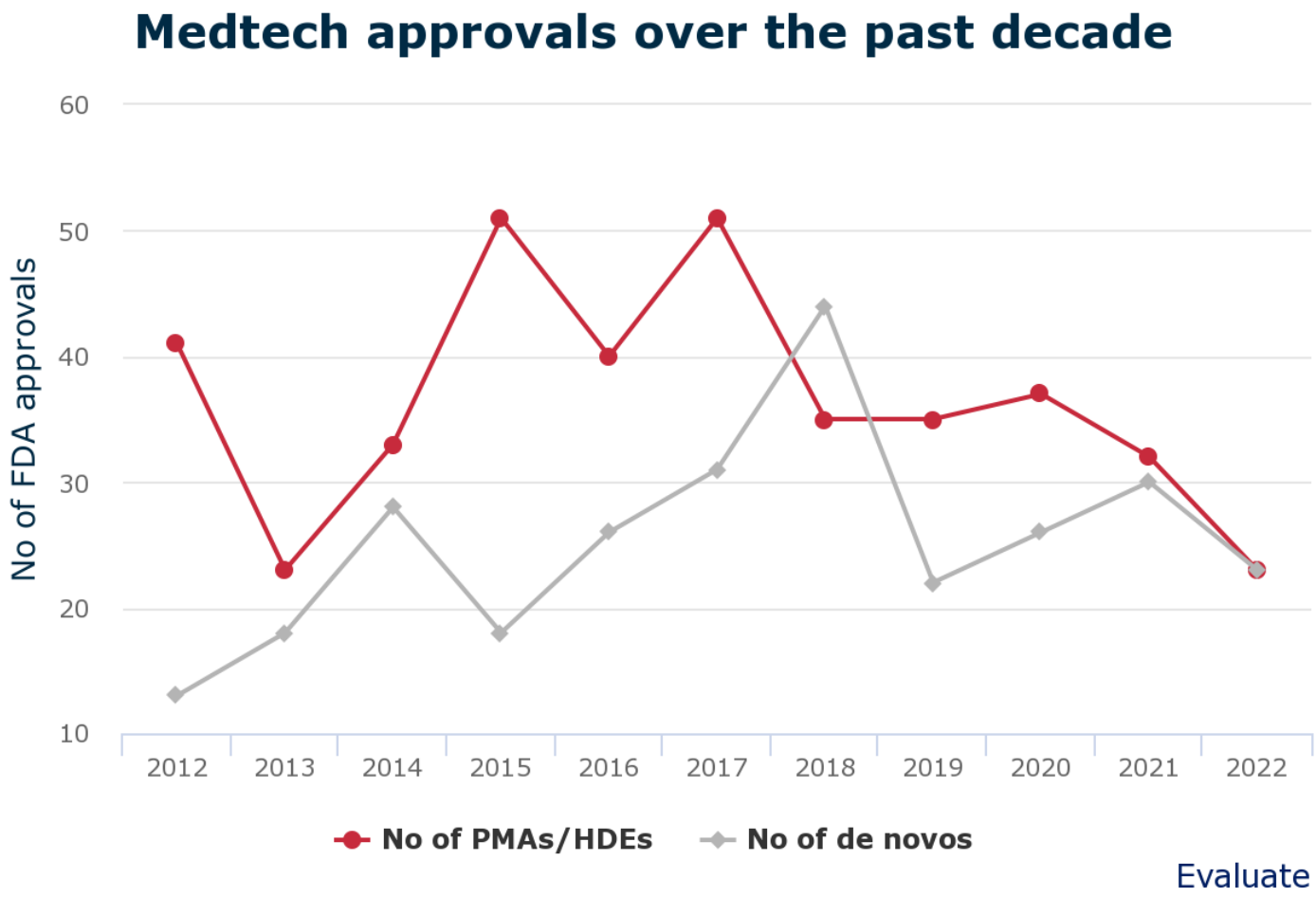
Device approvals hit a nine-year low in 2022, as the FDA takes its foot further off the gas.

At the halfway point of 2022 there was hope that the FDA's efforts to increase throughput might lead to an uptick in medical device approvals. However, this optimistic scenario did not play out, and the 46 green lights last year represented the lowest total since 2013.

These approvals also took a relatively long time to come through – although the regulator picked up speed in the second half of the year. With medtech M&A and IPOs faltering amid a broader market malaise, a pick-up in approval numbers will be needed to convince investors of the underlying health of the sector.

This analysis looks at premarket approvals – the route used by high-risk devices unlike anything yet approved – and de novo clearances – the pathway for similarly novel low-risk products. Standard 510(k)s and supplemental approvals are not covered.



The 23 PMAs and humanitarian device exemptions took 17.8 months on average, the greatest lag between submission and approval since 2016. Meanwhile, the 23 de novos took a mean 12.7 months.

These are both slower than the speeds seen in 2021, which themselves represented a deceleration from 2020, the peak pandemic year. Such a dropoff is to be expected, with the FDA warning in late 2021 that it was under strain after being deluged by requests for emergency use authorisations.

Still, approvals are taking longer now than pre-pandemic, and industry watchers will not want this trend to continue.

2022's approvals by therapy area

	PMAs & HDEs		De novos	
Evaluate Medtech classification	**Number**	**Avg approval time (mths)**	**Number**	**Avg approval time (mths)**
Anaesthesia & respiratory	2	14.9	2	7.8
Cardiology	8	23.0	-	-
Endoscopy	-	-	3	8.6
In vitro diagnostics	6	11.9	7	18.2
Neurology	2	24.4	1	7.4
Ophthalmics	2	22.5	1	19.0
Orthopaedics	2	6.3	2	8.9
Total	**23**	**-**	**23**	**-**
Average	**-**	**17.8**	**-**	**12.7**

Note: table only shows areas with at least three approvals. Source: Evaluate Medtech, FDA.

As previously noted, the device with the most tortuous path to approval was Abbott's leadless pacemaker Aveir VR, which took over six years to get its PMA.

Other cardiology products had a much smoother ride. Notably, Edwards' Pascal mitral valve repair system got the nod in September after a review that took just six months. The group could find it tough going up against Abbott's MitraClip, however.

The devices that got to market quickest in 2022, in 4.9 months, were Medtronic's Prodigi traction magnet, used in endoscopic submucosal dissection, and Phagenesis's Phagenyx neurostimulation system for dysphagia.

The in vitro diagnostics sector saw the highest number of approvals in 2022, boosting hopes that things are returning to normal after a couple of years in which the FDA prioritised Covid tests.

Faster review times have also been promised with the Mdufa V agreement signed into law in October. This must all be borne out with a rebound in approval numbers – and the speed at which they are granted – in 2023.