Evaluate Vantage

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More, but slower, medtech approvals

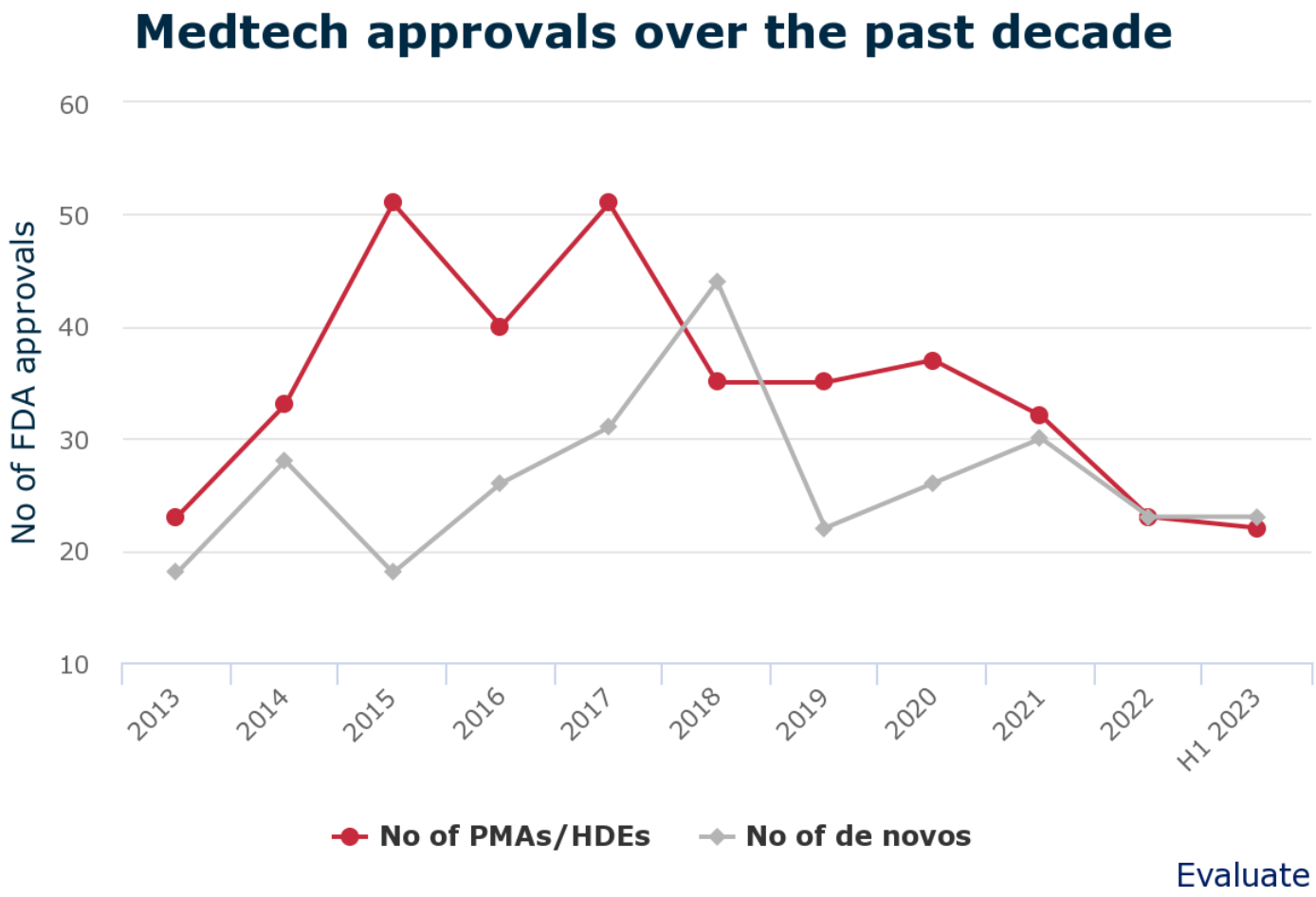
Elizabeth Cairns

If the second half maintains the pace, 2023 could see the most device approvals for a decade.

The FDA's Center for Devices and Radiological Health seems to have pulled its socks up. The medical device regulator granted approval or clearance to 45 innovative products in the first half of 2023 – only one less than in the entirety of 2022.

The caveat is that these were slower. The agency took an average of nearly three years to grant the 22 approvals for high-risk devices, a much longer average period than in prior years. Two of these devices had been awaiting approval for over a decade.

This analysis covers: premarket approval, the means by which medical devices that sustain or support life or are implanted are approved; humanitarian device exemption, awarded to a device if it treats a condition that affects fewer than 8,000 individuals in the US per year; and de novos, used for safer devices that would usually receive clearance via the 510(k) route, but which are so unlike previously approved devices that a predicate cannot be found.



The poor showing of the FDA's devices unit in 2022 has been thrown into reverse this year, and the reasons are clear. Last year's low total was partly a fallout from the Covid pandemic, which saw the agency regulate devices – mainly diagnostic tests, but also systems like ventilators – via the emergency use authorisation pathway. But the public health emergency caused by the virus was formally ended on 11 May this year.

Since medtechs knew that this moment was approaching, the rate of EUA applications had been slowing for some time. The FDA had thus been able to pivot to evaluating traditional approvals for several months before the state of emergency actually lapsed.

Moreover, several groups had moved to convert the EUAs their products already had to full approvals, which also bumped the total up. Four Covid diagnostics gained de novo clearance in the first half of 2023 – three from Quidelortho and one from Cue Health. All were the same as, or slightly tweaked versions of, tests that had previously gained emergency authorisation for Covid.

Turning on the Tap

As encouraging as it is to see an uptick in the number of innovative systems reaching the US market, it is perhaps somewhat concerning that the average time it has taken the agency to review these devices has lengthened considerably. From 2013 to 2022 the FDA took an average of 16.4 months to grant PMAs and HDEs. The figure for those granted this year is twice that.

De novos have also come more slowly in the first half of 2023 than in 2013-22, though at 13.6 months versus 11.6 the difference is not as stark.

But the agency is moving to speed things up. On 1 January it launched the Total Product Lifecycle Advisory Program (Tap), an initiative aimed at shortening review times by offering swifter responses from the FDA during the premarket process.

The Tap will not have had time to make its effects felt yet, but it could help the agency review innovative devices more rapidly in future.

H1 2023'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	28.9
Cardiology	6	55.7	-	-
General & plastic surgery	-	-	2	10.5
General hospital & healthcare supply	-	-	3	13.4
In vitro diagnostics	3	32.1	7	16.3
Neurology	2	43.8	3	10.3
Ophthalmics	2	9.1	-	-
Orthopaedics	3	14.7	2	10.5
Radiology	-	-	2	8.1
Wound management	2	12.3	-	-
Total	**22**	**-**	**23**	**-**
Average	**-**	**32.7**	**-**	**13.6**
Note: table only shows areas with at least two approvals. Source: Evaluate Medtech & FDA.				