Evaluate Vantage

January 19, 2021

Focus on Covid-19 does not distract the FDA

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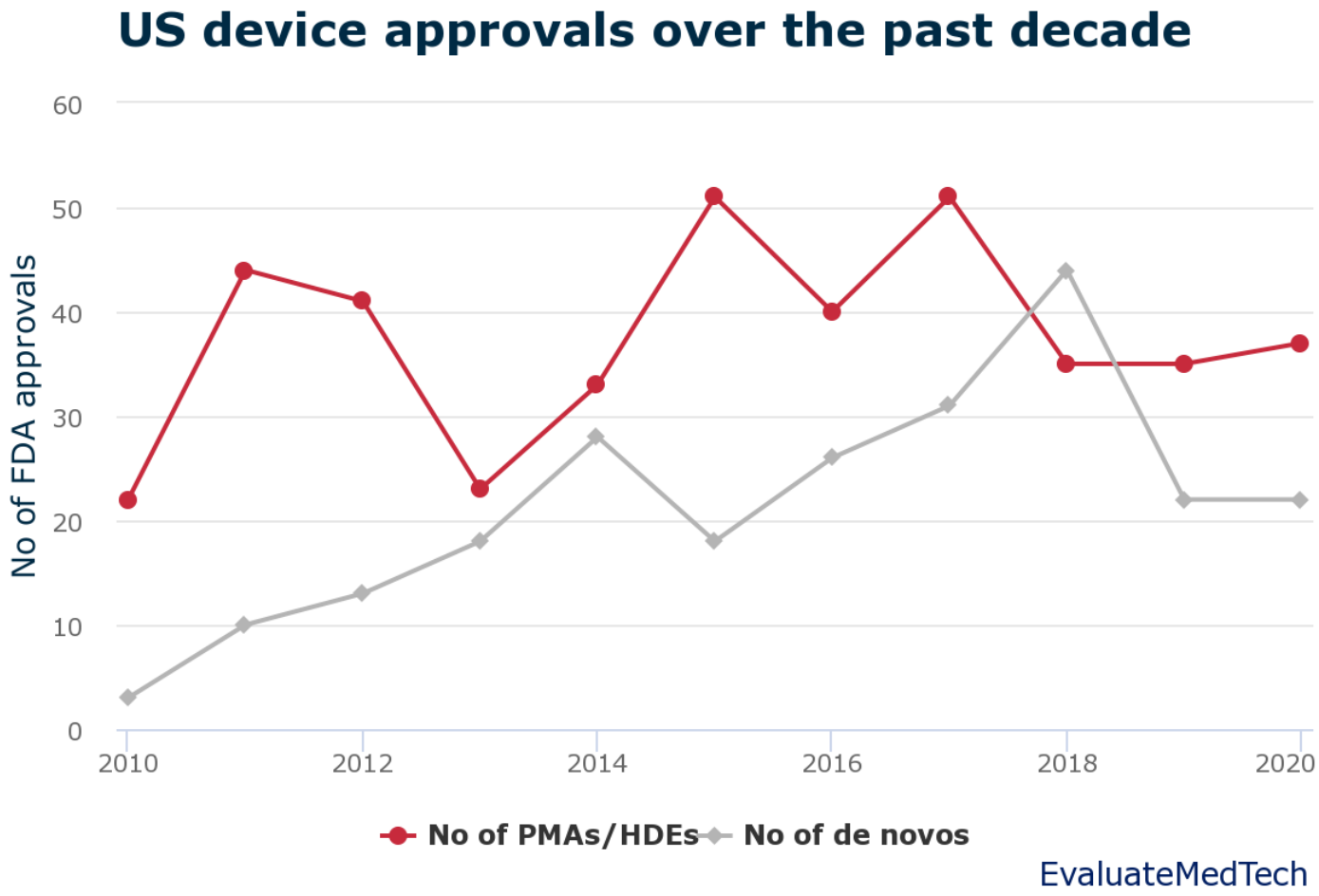
Non-Covid-19 medical device approvals tick up alongside the agency's pandemic efforts.

Not bad, considering. The number of innovative medical devices approved or cleared by the US FDA over the course of 2020 remained pretty steady from the year before, despite the Covid-19 pandemic putting huge pressure on the agency to get new products and diagnostics to market swiftly via a new regulatory path: the emergency use authorisation.

On top of this business as usual, the FDA has overseen the path to market of nearly 300 tests for Covid-19 infection or related technologies, such as sample collection kits. It also granted EUAs to hundreds of other medical devices including ventilators and personal protective equipment. With the end of the pandemic now just about in sight, the FDA has in fact done an impressive job.

At 37, the number of first-time premarket approvals, which are granted to high-risk innovative medical technologies, just pipped 2019's figure of 35, and de novo 510(k) clearances, granted to low-risk products, held constant at 22.



But these approvals were clustered in particular therapeutic areas. Devices in just six different therapeutic classifications were granted PMAs in 2020, versus nine different areas in both 2019 and 2018.

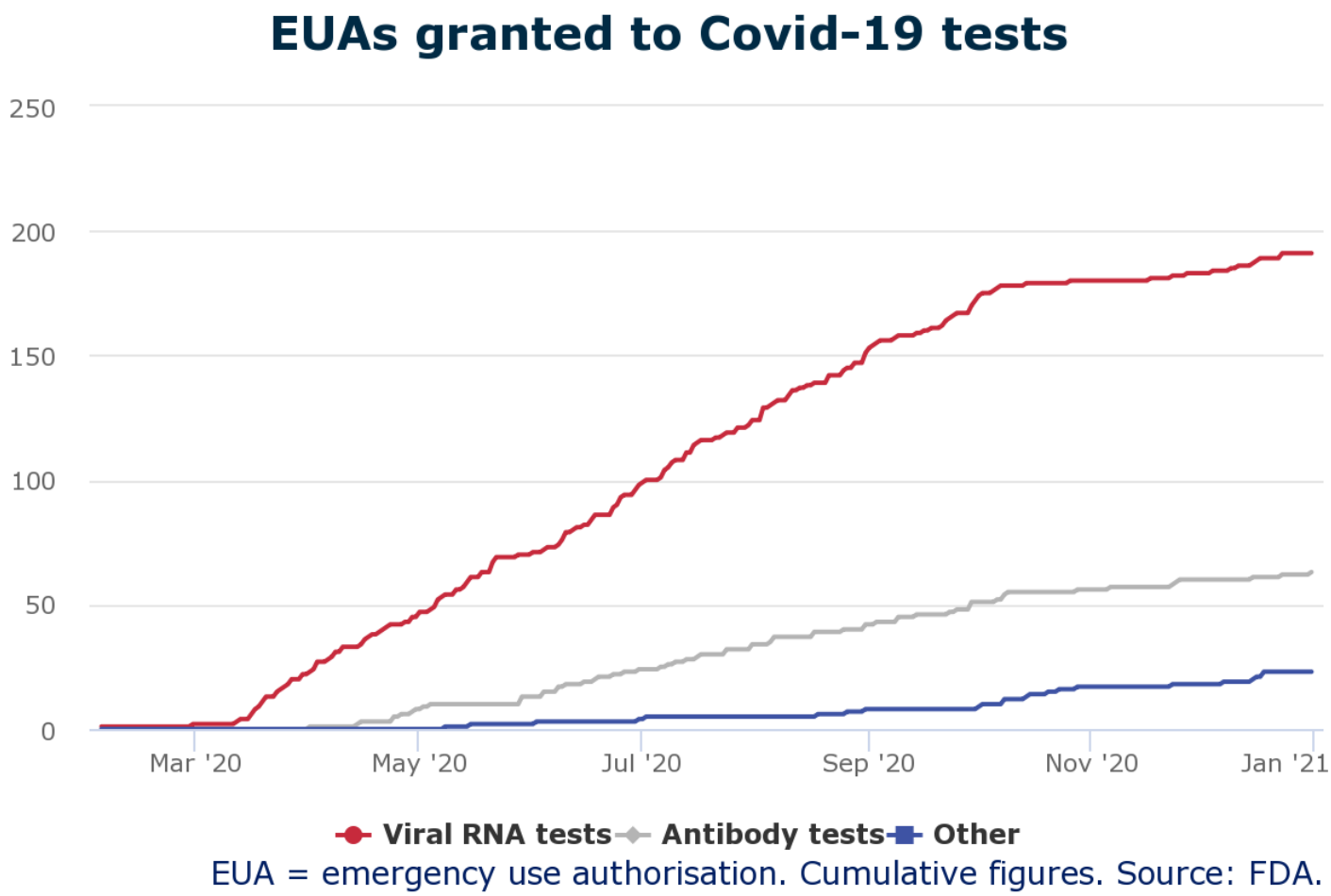
And diagnostics are way out in front. 23 different high-risk and seven low-risk assays were approved or cleared last year, 62% and 32% of the total PMAs and de novos respectively. None of these were for Covid-19 – the only route to market for coronavirus tests in 2020 was via emergency authorisation.

2020's approvals by therapy area				
EvaluateMedTech classification	**Number of PMAs**	**Avg approval time (mths)**	**Number of de novos**	**Avg approval time (mths)**
Cardiology	9	14.9	3	12.0
Diagnostic imaging	-	-	1	5.4
Dental	-	-	1	12.9
Gastroenterology	-	-	1	6.9
In vitro diagnostics	23	12.2	7	9.0
Nephrology	-	-	2	15.0
Neurology	1	9.6	2	3.7
Ophthalmics	1	5.9	2	10.0
Orthopaedics	2	9.3	2	11.8
Urology	1	30.0	1	10.8
Total	**37**	**-**	**22**	**-**
Average	**-**	**12.9**	**-**	**9.8**
Source: EvaluateMedTech, FDA.				

Instead they were mostly for other sorts of infections. The Italian company Diasorin gained PMAs for a host of hepatitis B and C diagnostics, and tests for HIV and human papillomavirus were also represented. A breath test for *H pylori* developed by the Emirati group Arj Medical rounded out the infection diagnostics.

The other seven diagnostics approved are designed to detect, or guide the treatment of, cancer. The most notable here were the two liquid biopsies, from Guardant Health and Roche, which gained their PMAs three weeks apart in the summer.

When it comes to Covid-19 tests, the FDA kept them coming right up to the end of the year, with Nirmidas Biotech's MidaSpot Covid-19 antibody test winning authorisation on New Year's Eve. The pace of authorisations undeniably slackened during the autumn, however. As the vaccine rollout continues, and hopefully accelerates under the new administration, demand for Covid-19 assays ought to shrink.



Note: "Other" includes 11 antigen tests, six home sampling kits, three saliva collection devices and three IL-6 tests.

And since the EUAs hold only as long as a public health emergency exists in the US – such a determination was made on January 31, 2020 and will likely hold for some months yet – it is possible that over the coming year the makers of some of these tests will obtain formal approval or clearance for their products, allowing them to stay on the US market after the emergency has passed.

The same goes for other products issued with EUAs last year. From face shields to dialysis machines, hundreds of devices able to help prevent the disease's spread or treat those suffering from its effects were ushered into hospitals and other critical settings. Many people will be hoping that this level of Covid-19-related regulatory activity will not be required in 2021, and FDA personnel will surely be among them.

Emergency authorisations for non-diagnostic Covid-19 devices	
Device category	**No of EUAs**
Blood purification devices	4
Continuous renal replacement therapy and haemodialysis devices	3
Decontamination systems for personal protective equipment	14
Infusion pumps	1
Remote or wearable patient monitoring devices	6
Respiratory assist devices	5
Ventilators and accessories	105
Personal protective equipment	216
Other medical devices	7
Total	**361**
Source: FDA.	