Evaluate Vantage

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FDA grants twice as many device approvals in half the time

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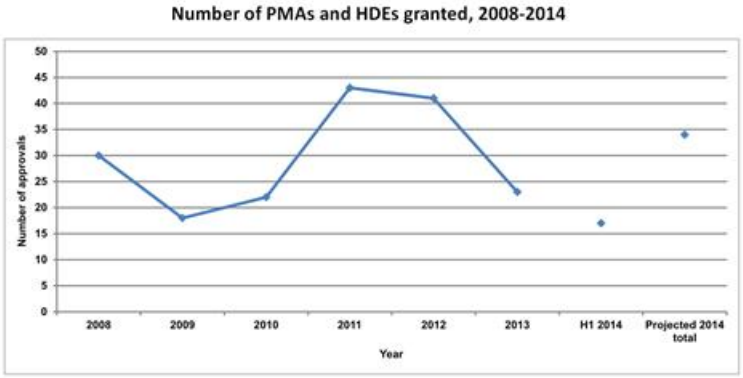
The pace of approvals at the FDA is picking up. This is good news for medtech companies after the fairly dismal showing in 2013, and suggests that the agency's efforts to bring new devices to market – exemplified by its plans to implement an expedited review process – might be having an effect.

The FDA awarded 17 first-time premarket approvals (PMAs) in the first half of 2014, up impressively on the nine in the first half of last year (see graph below). And with an average review time of 18.4 months – an admittedly fairly crude metric, but illustrative nonetheless – the devices have been assessed almost twice as rapidly as in the same period last year, when it took the FDA an average of 35.9 months to grant its PMAs.



That said, if the trend continues there will be 34 PMAs this year, which will still be down on the 39 seen in 2012 and the 42 in 2011. There is always a certain amount of fluctuation in this figure, but 2013 was a disappointment to many, particularly given the relative liberality with which CE marks are issued in Europe.

Faster

This is why the FDA is considering allowing a faster, simpler approval process for devices capable of treating diseases for which no therapy currently exists (*Vantage Point – New FDA expedited review could halve the cost of device development, May 13, 2014*). The idea is that this process will be a rough analogue of the breakthrough designation that has aided drug approvals over the last couple of years.

There is also the existing *de novo* and human device exemption (HDE) routes, which allow faster approval and a lower bar of evidence of efficacy respectively. The most recent de novo approval went, in late June, to ReWalk Robotics for its powered exoskeleton. No HDEs have been awarded so far in 2014.

As it is, the medal for swiftest PMA review goes to Medtronic's transcatheter aortic valve CoreValve with a turnaround time of just 5.8 months. The approval came six months earlier than even the company itself had expected (*EP Vantage interview – Medtronic aims to build on CoreValve approval, January 23, 2014*).

Arch-rival in this space and current US market leader Edwards Lifesciences has managed to fight back, however, with its next-generation Sapien XT aortic valve. This was approved in June, 13.5 months after submission, having been expected to reach market at around the same time as CoreValve; Medtronic doubtless made the most of this five-month window.

Relaxed

It might be thought that Anika Therapeutics received the booby prize as the FDA took more than four years to

be convinced of the merits of its hyaluronate-based osteoarthritis therapy Monovisc. But Monovisc had already been rejected twice, and the project had been all but written off by Anika's investors, so it actually represented a kind of victory; the company's stock jumped on the approval and even now is up 39% over the pre-approval price (*Anika rockets on unforeseen Monovisc approval, February 26, 2014*).

In a sense then, both the fastest and slowest approvals are indications of the FDA's increasingly relaxed stance. If the planned programme of expedited review of medical technologies comes into force this year, the second half could see even more approvals and even shorter submission-to-approval timelines.

If the FDA makes good on its promises, 2014 could see more innovative devices reach the US than ever before.

First-time PMAs granted by the FDA in the first half of 2014

Device Name	EvaluateMedTech Device Classification - L1	EvaluateMedTech Device Classification - L3	Company	Number	Decision Date	Review Time (Months)
ReSure	Ophthalmics	Other Ophthalmic Surgical Devices	Ocular Therapeutix	P130004	January 8, 2014	11.0
CoreValve	Cardiology	Transcatheter Heart Valves	Medtronic	P130021	January 17, 2014	5.8
Monovisc	Orthopedics	Viscosupplementation	Anika Therapeutics	P090031	February 25, 2014	49.9
Elecsys HBeAg Immunoassay and Elecsys PreciControl HBeAg	In Vitro Diagnostics	Viral Immunoassays	Roche	P130015	March 14, 2014	9.3
Nucleus Hybrid L24	Ear, Nose & Throat	Hearing Implants	Cochlear	P130016	March 20, 2014	9.5
Supera	Cardiology	Peripheral Vascular Devices	Abbott Laboratories	P120020	March 28, 2014	16.3
Inspire II upper airway stimulator	Anesthesia & Respiratory	Other Anesthesia & Respiratory Therapeutic Devices	Inspire Medical Systems	P130008	April 30, 2014	12.0
Sinovial	Orthopedics	Viscosupplementation	IBSA Institut Biochimique	P110005	May 9, 2014	38.9
Advia Centaur HBsAgII	In Vitro Diagnostics	Viral Immunoassays	Siemens	P110041	May 16, 2014	28.8
PreciseType	In Vitro Diagnostics	Hematology Molecular Diagnostics	Immucor	BP130026	May 21, 2014	11.3
Therascreen KRAS RGQ PCR kit	In Vitro Diagnostics	Oncology Molecular Diagnostics	Qiagen	P110027	May 23, 2014	34.0
CardioMEMS HF	Cardiology	ECG Monitoring	St. Jude Medical	P100045	May 28, 2014	41.4
Artus CMV RGQ MDx kit	In Vitro Diagnostics	Infectious Disease Molecular Diagnostics	Qiagen	P130027	June 2, 2014	5.9
Sapien XT	Cardiology	Transcatheter Heart Valves	Edwards Lifesciences	P130009	June 16, 2014	13.5
FluencY Plus	Cardiology	Graft Prosthesis	C. R. Bard	P130029	June 17, 2014	5.9
Freedom SOLO	Cardiology	Tissue Heart Valves	Sorin	P130011	June 24, 2014	13.3
Rebel	Cardiology	Non-Drug-Eluting Coronary Stents	Boston Scientific	P130030	June 27, 2014	5.9

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