MEDTECH INSIGHT
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US Approvals Analysis: July A Good Month For PMAs; 510(k)s Down In 2016

by David Filmore

A look at *Medtech Insight*'s Approval Tracker data shows that last month was a relatively active one for US FDA approvals of novel devices via the PMA, panel-track supplement and *de novo* routes. But 510(k) clearance totals are down so far in 2016 compared to recent years.

In July, the US FDA had its most active month of 2016 so far in approvals of novel device or indications, with 10 original and panel-track PMAs OK'd during the month, and another three *de novo* classifications finalized, according to *Medtech Insight*'s Approval Tracker.

The agency surpassed its performance from April of nine original and panel-track PMAs and three *de novos*. So far in 2016, through July, FDA has approved 25 original PMAs, 13 panel-track supplements and 13 *de novos*. That's in-line with the agency's approval of novel devices in 2015, a record-setting year, when there were 27 original PMAs approvals, nine panel-track supplements and 10 *de novos* approved through July.

Source: *Medtech Insight*

Product Category	Approvals
Cardiovascular	5
IVD	2
Neurology	2
Ophthalmic	2
Orthopedic	2

Among devices approved in July were *WL Gore & Associates Inc.*'s *Gore Tigris* vascular stent for peripheral artery disease and *Novartis AG*/*Alcon Research Ltd.*'s *Cy-Pass Micro-stent* for use in conjunction with cataract surgery for the reduction of intraocular pressure in adult patients with mild-to-moderate primary open-angle glaucoma. Alcon acquired the technology in its February-

announced acquisition of Transcend Medical Inc.

A noteworthy panel-track supplement from last month was *the approval* of *Medtronic PLC*'s *Prestige LP* artificial disc for two-level cervical reconstruction. One July *de novo* classification, a pathway used for moderate-risk devices with no market predicate, went to *Micro Interventional Devices Inc.*'s *Permaseal* for transapical access and closure in structural heart repair. (Also see "*Transcatheter Mitral Valve Therapy: Opportunities And Challenges*" - Medtech Insight, 15 Dec, 2015.)

Novel cardiovascular devices were the most frequently approved in July. There were approvals of *in vitro* diagnostics, neurology devices, and products in ophthalmics and orthopedics.

510(k) Clearances Down In 2016

Meanwhile, FDA is on a slower pace of 510(k) clearances so far in 2016 compared to recent years. The US agency cleared 236 510(k)s last month, for a total, through July, of 1,696 clearances this year. That is compared to 1,812 in the first seven months of 2015 and 1,858 clearances in the same period of 2014.

Device 510(k)s cleared in July include Meril Life Sciences' *Mozec NC-Rx* PTCA Balloon Dilatation Catheter and Next Orthosurgical's *VertiForm* posterior fixation system.

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Outside the US, it was a relatively light month for European CE marks and approvals in other regions, according to the Approvals Tracker. (Also see "*OUS Approvals Analysis: Summer Brings Slowdown In CE Marks*" - Medtech Insight, 5 Aug, 2016.)

For sortable and searchable tables of all 2016 US and non-US approvals and clearances, check out the Approvals Tracker: *https://medtech.pharmamedtechbi.com/datasets/approvals*.

From the editors of The Gray Sheet