MEDTECH INSIGHT
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07 Oct 2016 | **Analysis**

US Approvals Analysis: Strong Q3 For Metabolic-Disease Devices

by David Filmore

Of the five original PMAs approved last month by US FDA, two target diabetes and one targets obesity. In addition, the agency granted a *de novo* classification to another obesity device. Overall, FDA had a productive third-quarter for approvals and clearances.

[Editors' note: *For sortable and searchable tables of all 2016 US and non-US approvals and clearances, check out our Approvals Tracker.*]

Products addressing metabolic conditions attracted the most attention from US FDA's novel device approval pathways in September.

Of the five *original PMAs* approved last month by the agency, two target diabetes and one targets obesity. In addition, FDA granted a *de novo* classification to another obesity device – one of three *de novos* in September.

Overall, the agency had a productive September in approving and clearing devices, hitting totals above 2016 averages for all main submission types. And the third quarter was FDA's most productive period of calendar year 2016 for original PMA and PMA supplement approvals, as well as 510(k) clearances, according to *Medtech Insight*'s *Approvals Tracker*.

Among the devices that made it through the most demanding FDA pathway – original PMA – was *Obalon Therapeutics Inc.*'s *Obalon* intragastric balloon, which was approved Sept. 8 for obese individuals with a body mass index of 30 kg/m^2 to 40 kg/m^2 who have failed to lose weight through diet and exercise. It will compete directly with two intragastric balloons approved last year – *ReShape Medical Inc.*'s *ReShape* balloon and *Apollo Endosurgery Inc.*'s *Orbera*. It will also go up against other recently approved, minimally invasive obesity systems. (Also see "*Obesity 2016: Minimally Invasive Bariatric Devices Gaining Steam*" - Medtech Insight, 20 Jul, 2016.)

But the most highly anticipated approval that came through in September was likely for *Medtronic PLC*'s *Minimed 670G* closed-loop insulin pump-continuous glucose monitor system, dubbed an "artificial pancreas." (Also see "*US FDA Approves First 'Artificial Pancreas' In Medtronic's MiniMed 670G*" - Medtech Insight, 28 Sep, 2016.) That historic approval followed soon after the agency's go-ahead for *Abbott Laboratories Inc.*'s *Freestyle Libre Pro* flash glucose-monitoring system. (Also see "*Abbott Gains US Approval For Pro Version Of Flash Glucose System*" - Medtech Insight, 28 Sep, 2016.)

There was also one original PMA approval for an oncology companion diagnostic – another win for *Roche*'s *cobas EGFR Mutation Test v2* assay, and another in ophthalmics, for *Carl Zeiss Meditec AG*'s *Visumax* femtosecond laser.

The *de novo classification process* has also been an increasingly popular pathway to bring completely novel devices to market if they can be shown to be moderate-risk rather than high-risk. Among the three *de novo* classifications in September, the agency granted market access to [Scientific Intake Ltd.]'s *Sensor Monitored Alimentary Restriction Therapy* (SMART) device on Sept. 26. SMART is a sensor-embedded custom-made oral device that is placed in the mouth only while eating to force smaller bites, require chewing and other adjustments to eating habits intended to reduce weight, and also to track weight-loss goals.

FDA also granted *de novo* clearance to *Johnson & Johnson*'s *Acclarent Aera* ear, nose and throat dilation system for treating eustachian tube dysfunction, and *Stryker Corp.*'s *Trevo ProVue* and *XP ProVue* as a *first-line therapy* for ischemic stroke.

Strong Q3 for PMA approvals, compared to past two years

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Approvals, Clearances Up In Third Quarter

De novo submission activity has been picking up since fiscal year 2013 when the law was changed to allow companies to access the pathway for moderate-risk devices without first needing to unsuccessfully pursue a 510(k). (Also see "*Successful De Novo Petitions Double With Advent Of Direct Route*" - Medtech Insight, 28 Oct, 2014.) There have been 17 successful *de novo* classifications in the first three quarters of calendar year 2016, up from 11 in the same period last year (but down slightly from the 20 classifications in September 2014).

There have been 32 original PMAs approved through the third quarter, just shy of the 33 approved at this time in 2015, which was a record-setting year. (Also see "*FDA Hits User-Fee-Era Record For 'Novel' Devices: A New Normal?*" - Medtech Insight, 14 Jan, 2016.) Meanwhile, FDA is ahead of recent-year performance for panel-track PMA supplement approvals. There were 18 panel-track supplements approved through September of this year, up from 12 and eight such approvals in the first three quarters of 2015 and 2014, respectively.

Approvals of *other types of PMA supplements*, not including 30-day notices, are also up so far this year, with 660 through September, compared to 576 during the same period last year.

510(k) clearances , the pathway used by most devices to reach the US market, are the only category that remains down in volume this year, with 2,209 clearances so far in 2016 compared to 2,297 in 2015. But the third quarter of 2016 was the most productive quarter for 510(k) clearances so far this year, as it was for PMAs and PMA supplements, as well.

From the editors of The Gray Sheet