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US approvals of innovative devices halve

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The US FDA has been under fire for some years from device manufacturers who insist that the agency's criteria for granting approvals are too strict. Medtech companies point to the lag between obtaining European CE mark and US approval, which is usually around three years, as evidence that the FDA's stringency is stifling innovation.

Analysis of *EvaluateMedTech* data shows that these protests are having little effect: the FDA granted just nine first-time premarket approvals (PMAs) in the first half of 2013, plus one humanitarian device exemption (HDE) – a 47% drop from the 19 PMAs issued in the first half of 2012.

Cardiology and in vitro diagnostics, perennially popular sectors for innovation, are the most-represented therapeutic categories for first-time PMAs – as opposed to PMA supplements, which are awarded for new versions of already-approved products – in 2012. Interestingly, though, PMAs for two breast implants mean that, so far in 2013, as many plastic surgery products have been approved as cardiology technologies (see tables).

First-time premarket approvals (PMAs) by therapy area, 2012 and 2013

EvaluateMedTech Device Classification - L1	Number of first PMAs FY 2012	Number of first PMAs H1 2012	Number of first PMAs H1 2013
Anesthesia & Respiratory	0	0	1
Cardiology	14	6	2
Diabetic Care	1	0	0
Diagnostic Imaging	3	2	0
Drug Delivery	1	1	0
Gastroenterology	1	1	0
General & Plastic Surgery	2	1	2
In Vitro Diagnostics (IVD)	13	7	3
Ophthalmics	2	1	0
Orthopedics	3	0	0
Radiology	1	0	0
Wound Management	0	0	1
Total	*41*	*19*	*9*

This unusual situation can perhaps be explained by the Poly Implant Prothèse scandal, where the French company's breast implants were found to contain industrial rather than medical-grade silicone. Last month's approval of the Mentor CPG breast implants means that there are now five FDA-approved silicone gel-filled breast implant products available in the US, manufactured by three companies: Allergan, Sientra and Mentor; the latter was acquired by Johnson and Johnson in 2009.

2013 also brings approvals in the respiratory and wound healing sectors, neither of which were seen last year. J&J's Sedasys device is the first computer-assisted personalised sedation system to be approved in the US for use by clinicians in endoscopy suites, and could end up putting the anaesthesiologist out of a job. The system administers propofol whilst monitoring sedation in patients undergoing upper and lower endoscopies.

As befits the largest medtech company, J&J is the only company to obtain PMA for two products so far this year.

The wound management device is a surgical sealant, ArterX, an elastic gel developed to seal suture holes formed during surgical repair of blood vessels. It can adhere to native tissues, as well as synthetic materials, including PTFE and Dacron grafts, and is largely resorbed within 12 months.

Bottleneck

Vascular repair is also the purpose of Vascade, a device developed by Cardiva to stop bleeding at femoral access sites for minimally-invasive interventional cardiology techniques. With catheter based procedures like renal denervation and the implantation of transcatheter heart valves growing in popularity, Vascade should have a strong future (*Therapeutic focus – Transcatheter aortic valves boosted by guidelines, October 1, 2012*).

Also in the cardiovascular field is Lombard Medical Technologies's Aorfix stent graft, the only such product approved for cases where the artery above the aneurysm bends particularly sharply. Lombard feels that this will give it an edge over other grafts even in patients who do not have particularly tortuous anatomy, as, once doctors start using it for the more acute cases, they will also use it in patients with straighter vessels (*EP Vantage interview – Lombard goes it alone, February 18, 2013*).

First-time PMAs and HDEs granted by the FDA in the first half of 2013

Device name	Company	EvaluateMedTech Device Classification Level 1	EvaluateMedTech Device Classification Level 3	Type of approval and number	Decision date
Vascade vascular closure system	Cardiva Medical	Cardiology	Vascular Closure Devices	PMA (P120016)	31 January 2013
Aorfix flexible stent graft system	Lombard Medical Technologies	Cardiology	Graft Prosthesis	PMA (P110032)	14 February 2013
Natrelle highly cohesive silicone-filled breast implants	Allergan	General & Plastic Surgery	Breast Prosthesis	PMA (P040046)	20 February 2013
ArterX surgical sealant	Tenaxis Medical	Wound Management	Surgical Sealants	PMA (P100030)	01 March 2013
Sedasys computer-assisted personalized sedation system	Johnson & Johnson	Anesthesia & Respiratory	Other Anesthesia & Respiratory Therapeutic Devices	PMA (P080009)	03 May 2013
cobas EGFR mutation test	Roche	In Vitro Diagnostics (IVD)	Oncology Molecular Diagnostics	PMA (P120019)	14 May 2013
THxIDTM-BRAF assay kit	bioMérieux	In Vitro Diagnostics (IVD)	Oncology Molecular Diagnostics	PMA (P120014)	29 May 2013
Mentor CPG breast implants	Johnson & Johnson	General & Plastic Surgery	Breast Prosthesis	PMA (P060028)	14 June 2013
Abbott RealTime HCV Genotype II, Abbott RealTime HCV Genotype II control kit, uracil-n-glycosylase	Abbott Laboratories	In Vitro Diagnostics (IVD)	Infectious Disease Molecular Diagnostics	PMA (P120012)	20 June 2013
Argus II retinal prosthesis system	Second Sight Medical Products	Ophthalmics	Other Ophthalmic Prosthetic Devices	HDE (H110002)	13 February 2013

One thing that is unsurprising is that all three IVDs approved in the first half are molecular diagnostics.

The most recently approved, Abbott's RealTime HCV Genotype II, is a laboratory test that can differentiate hepatitis C genotypes 1, 1a, 1b, 2, 3, 4, and 5 in a sample of plasma or serum from a chronically infected

individual. Hep C is the most common chronic blood-borne infection in the US and the leading cause of liver transplants.

With Gilead's sofosbuvir heading to market with enormous expectations, not least related to its ability to treat the especially tricky genotype 1, Abbott's test could do well (*Asco propels PD-1s into most valuable asset rankings, July 24, 2013*).

The other two IVDs are companion diagnostics for cancer drugs: bioMérieux's BRAF diagnostic can assess a patient's suitability for GlaxoSmithKline's melanoma drugs Mekinist and Tafinlar, whereas Roche's EGFR mutation test can determine whether a non-small cell lung cancer patients will benefit from treatment with Roche's own Tarceva.

In vitro diagnostics is one area on which the FDA's grip is tightening, with plans to increase regulation of so-called home-brew tests (*Vantage Point – FDA regulation of lab-developed tests could hurt smaller companies, June 19, 2013*). If this comes to pass, bioMérieux and Roche, as companies whose tests have already been passed by the FDA, could stand to gain.

Humanitarian device exemption

If a first-time PMA is an indication of a device's innovative nature, a humanitarian device exemption is doubly so. An HDE is similar to a PMA, but is exempt from effectiveness requirements; put bluntly, the company is not required to submit clinical results proving that the device works. Instead, the FDA must be convinced that the probable benefit to health outweighs the risk of injury or illness the device poses, that no comparable devices that treat or diagnose the condition yet exist, and that the manufacturer could not otherwise bring the device to market.

The Argus II retinal prosthesis developed by Second Sight Medical Products apparently meets these criteria. It is the first implanted device to treat adults with severe retinitis pigmentosa, and consists of an electronic device implanted in and around the eye, a tiny video camera attached to a pair of glasses, and a video processing unit that is worn or carried by the patient. The camera films the world around the patient and the signal is transmitted wirelessly to the eye where it stimulates the retina, which is recognised by the brain as spots of light.

Second Sight claims that the Argus II can help patients walk, identify objects and people and read large-print words.

If the FDA is getting stricter on CLIA-waived tests, it might be well advised to relax its stand overall. With just nine PMAs and one HDE granted so far this year, the bottleneck appears to be becoming even more of a problem. Device makers must hope that the second half of the year brings better news from the FDA.

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