



2015

# Medtech Half-Year Review

Elizabeth Cairns & Madeleine Armstrong – July 2015







# EP Vantage Medtech Half-Year Review 2015

The first half of 2015 has seen some seismic changes to the medtech industry. Most obviously the sector has a new leader, with Medtronic displacing Johnson & Johnson as the company with the largest sales of medical technologies.

Medtronic's \$50bn purchase of Covidien also makes up the vast majority of the total value of mergers closed in the first six months. At \$83bn this total is greater than that for any six-month period – and, incredibly, any full-year period – ever. It also puts 2015 on track to break the \$100bn barrier in terms of the total value of mergers closed.

Then there is the medtech IPO market, which appears to be stabilising. While early 2015 looks disappointing compared with last year's listing frenzy, there were still more IPOs on Western exchanges in the first half of this year than in all of 2013, suggesting that the market is not slipping back to the doldrums.

The most worrying finding is that venture financing, never easy for device companies to come by, has become even scarcer. The second quarter of 2015 saw the lowest total VC investment for a second quarter for seven years – important as the second quarter usually sees a larger haul than the others in any calendar year.

While all companies are facing this squeeze, early-stage businesses appear to be the most affected as VCs look for surer bets at later stages of development, leaving them lacking seed funding. Some start-ups are beginning to turn to less orthodox sources of cash such as corporate VCs investment and crowdfunding to meet the shortfall, but if these funding patterns continue, 2015 could still be very sticky indeed for young medtech companies.

Medtech groups in general have had a tough time on the stock exchanges as various pressures came to bear, including disappointing financial results and the impact of spin-outs. Some large-cap companies saw their share prices decline in the first half – the first time this has happened in two years. Perhaps this is a reality check for those that have had an easy time of it while smaller firms struggled.

A ray of sunshine comes from the FDA. The regulator has granted first-time premarket approvals or humanitarian device exemptions for 26 devices so far this year, and if this rate continues more innovative products could reach the US market than in any year since at least 2005.

This could be down to more productive companies, or an FDA that is increasingly willing to work more closely with medtech firms. One thing seems certain: with the agency making efforts to speed US approvals further, this rate should be maintained as these new measures filter through.

There are rewards, then, for the companies that make it past the very early stages. The crunch comes during the start-up phase, and while this has always been true of the medtech sector, and indeed business in general, the situation does seem to be worsening. It is crucial for the funding gap to ease if a steady flow of safe and effective medical technologies is to be maintained.

Unless stated, all data are sourced to EvaluateMedTech and were accessed in July 2015.



## Mergers to hit \$100bn by year-end?

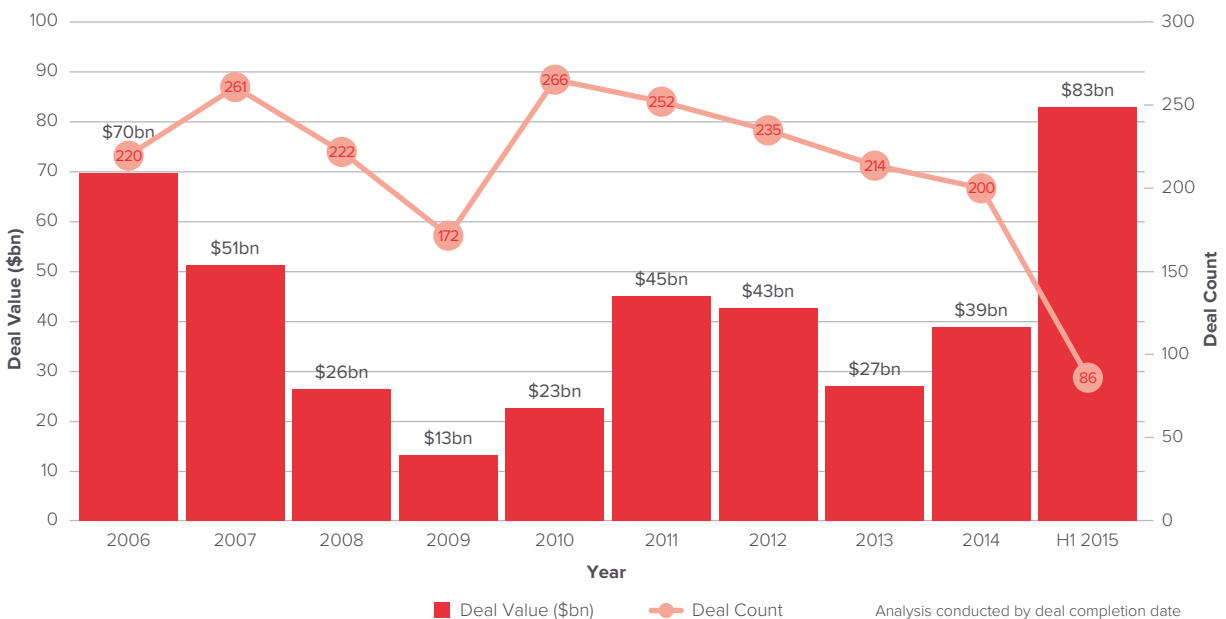
The first half of 2015 saw 86 mergers and acquisitions in the medtech industry – a pretty average number for the first half of a year. The figure for the total value of mergers closed, however, is anything but average: at \$83bn, it dwarfs even the full-year figures for the past decade and is without question the highest total ever recorded. At year-end, 2015 could see closed deals worth more than \$100bn for the first time ever in the sector.

The biggest acquisition in the sector's history, that of Covidien by Medtronic for \$50bn, makes up the lion's share of the total, though sizeable buys by Zimmer and Becton Dickinson played their part. It will be many years before this total is surpassed.

With many of the mid-stage players already acquired or merged, the future ought to see a return to the more measured pace of deal-making seen in prior years, and this is no bad thing.

### Medtech M&A Activity

Source: EvaluateMedTech™ July 2015



There are few discernible patterns among the biggest takeouts this year. They cover disparate technological areas – from cardiology to diagnostics, respiratory to drug delivery – and, while the two biggest deals were about building scale and consolidation, others have involved a company moving into an entirely new area. Eurofins had little to do with in vitro testing before it bought Boston Heart Diagnostics, for example.



After the \$10bn-plus megadeals it is interesting to see the fourth and fifth places taken by divestments from the same company: Siemens. The German conglomerate has performed poorly over recent years, and selling its hospital IT business to the medical records company Cerner and its hearing aids to a private equity group, EQT Partners, is part of a plan to refocus on higher-margin areas.

### Top 5 takeouts closed in H1 2015

Source: EvaluateMedTech™ July 2015

Acquirer	Target	Value (\$bn)
Medtronic	Covidien	49.9
Zimmer	Biomet	14.0
Becton Dickinson	CareFusion	12.2
EQT Partners	Audiology Solutions business of Siemens	2.7
Cerner	Siemens Health Services	1.3

The imaging rival Philips is also reshaping its business, but is taking a different approach. Rather than narrowing its focus, the Dutch company is actually expanding its reach, at least when it comes to healthcare. Its new health tech offering will encompass traditional medtech as well as related consumer devices, with Philips' goal to address the whole "healthcare continuum". And, also unlike Siemens, Philips is getting out of non-health-related areas and is in the process of offloading its lighting division.

Philips closed its own megadeal in the first half, purchasing the interventional imaging specialist Volcano for \$1.2bn. As well as allowing it to move into a new and complementary sector, Philips will be hoping that it bagged a bargain in the somewhat troubled Volcano, which had been knocked badly by missed revenue forecasts, and was in the grip of investor activism when Philips stepped in.

### Top 5 takeouts closed in 2014

Source: EvaluateMedTech™ July 2015

Acquirer	Target	Value (\$bn)
Thermo Fisher Scientific	Life Technologies	13.6
Carlyle Group	Ortho-Clinical Diagnostics	4.2
Danaher	Nobel Biocare	2.2
Essilor International	Transitions Optical	1.9
Grifols	Blood transfusion diagnostics business of Novartis	1.7

The larger deals have been contracted for the now-familiar reasons: it is increasingly important for a company to have as wide a range of products as possible so that hospitals and other payers can use it as a single supplier for all their needs – at least in a particular area, such as interventional cardiology or prosthetic joints. Companies may also arrange defensive acquisitions to guard against being bought themselves, but this is less common than in the biopharma arena.

Be that as it may, the reason 2015 will be remembered is the Medtronic deal. It was the first in a decade to top \$20bn, and will almost certainly hold the top spot for another 10 years or more.



## Venture financing crisis worsens

What has long been suspected is now confirmed: VC funds are losing interest in medical devices. Just \$1.6bn was raised in total in the first half, a pretty woeful figure even by the standards of recent years, which have themselves seen falling levels of investment.

Medtech was once seen as a more solid bet than biotech, with shorter approval cycles and therefore the prospect of a quick exit for VCs. However, the exit is not always that simple; while product approval used to be enough to tempt a potential buyer, now a company might need to get its device reimbursed and see a ramp up in sales before becoming an attractive prospect.

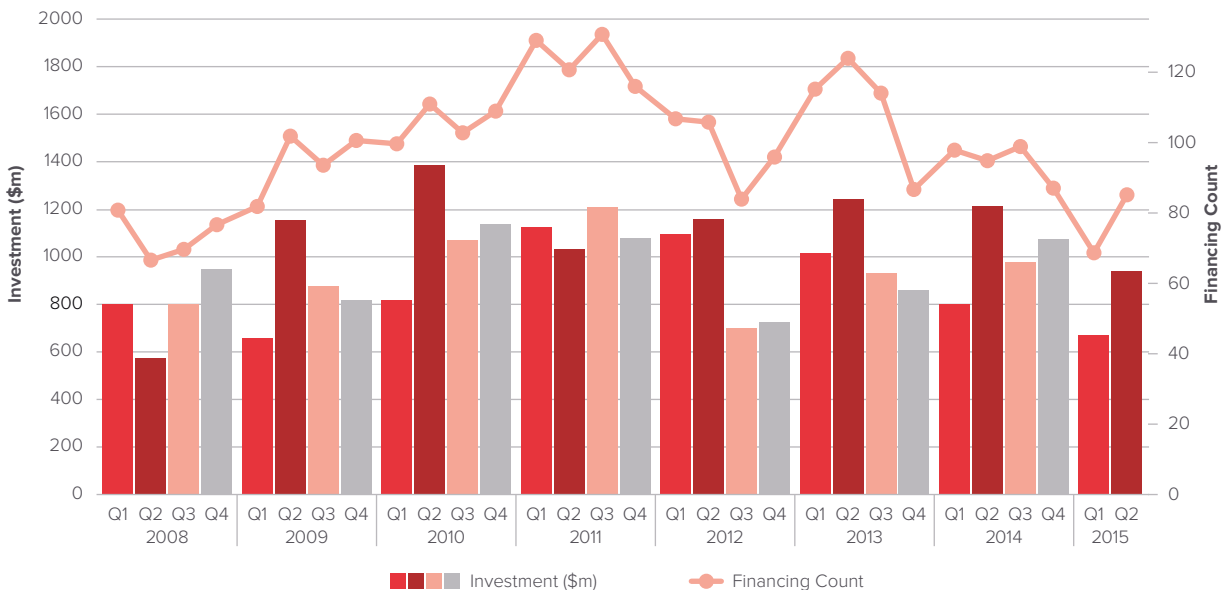
Device makers' dwindling appeal seems inversely proportionate to the current biotech bull run. Perhaps investors are being seduced by the rich returns of biotech, in spite of the higher risk, at the expense of medtech. Tech companies could also be providing competition, and with the convergence of these two areas – witness Apple and Google's efforts to push into health – VCs who had previously favoured medtech might go for computing instead.

The so-called Valley of Death is these days more of an abyss. The downturn in venture funding of which medtech start-ups have long complained is now so pronounced that the second quarter of 2015 saw the lowest total haul for any second quarter since post-crash 2008.

This is significant as the second quarter is usually the richest three-month period of the calendar year. Unless the second half of 2015 sees markedly more venture capital flowing into the industry 2015 could be the poorest year – in both senses – since 2006.

### Quarterly Medtech VC Investments

Source: EvaluateMedTech™ July 2015





Unlike earlier periods the first half of this year has not been enlivened by any exceptional successes. In the first half of 2014 there were three rounds of \$100m-plus, but this time no company has broken the \$60m mark.

The leader this time is the genetic testing company Natera, which in April drummed up \$56m, which it said it would use to grow its sales force and invest in R&D, including the development of its prenatal blood test Panorama, used to detect foetal chromosomal abnormalities in a sample of a pregnant woman's blood.

The fact that the round was led by the Silicon Valley-based crossover fund Sofinnova Ventures, though, showed that the series F was a pre-IPO round. Sure enough, the company raised an impressive \$180m when it floated in the first week of July.

Prenatal testing of this type is growing in popularity, with insurers beginning to cover it for women at high risk of carrying foetuses with genetic illnesses. Recent hints that some of these tests, though not Natera's, can also pick up signs of cancer in the women themselves might expand the market further.

### Top 10 rounds of H1 2015

Source: EvaluateMedTech™ July 2015

Company	Financing round	Investment (\$m)
Natera	Series F	55.5
Calhoun Vision	Undisclosed	52.0
Outset Medical	Undisclosed	51.0
Guardant Health	Series C	50.0
Shockwave Medical	Series B	40.0
Intact Vascular	Series B	38.9
Autonomic Technologies	Series D	38.0
Scanadu	Series B	35.0
Auxogyn	Series C	34.3
Neuronetics	Series F	34.3

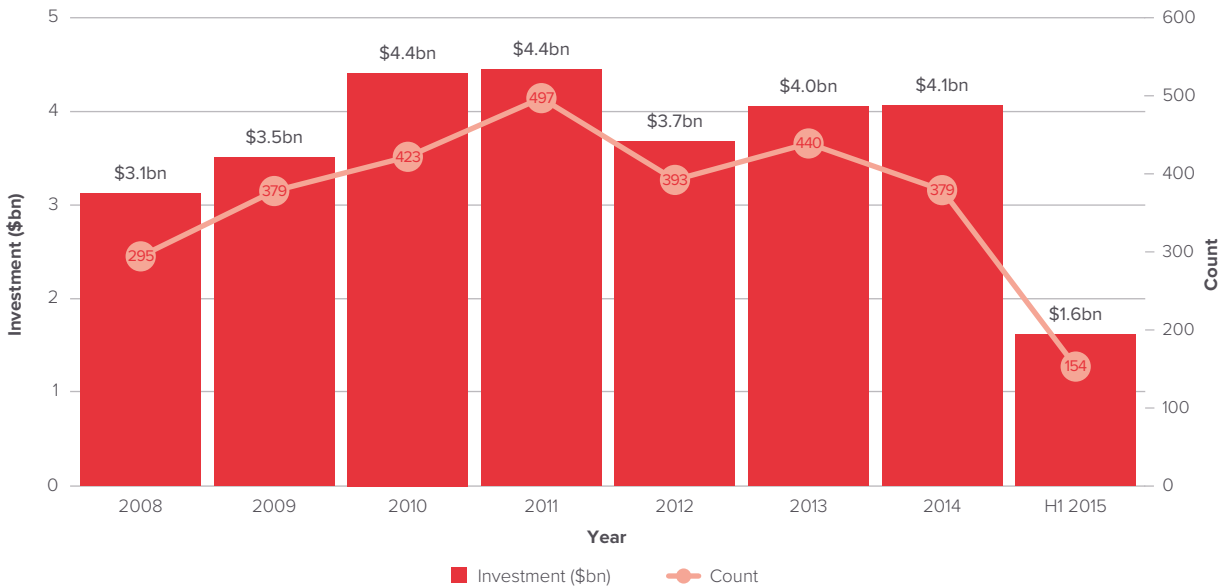
The companies that raised the biggest rounds tend to have a recognisable technology with a clear market opportunity and without heavy up-front costs. But still they are not rewarded with the kind of sums seen in the past.

Medtech start-ups have been bemoaning a paucity of VC funding for the past couple of years, and a look at the annual figures shows that their complaints have merit. In large part this is due to venture capital firms fighting shy of risk. Increasingly VCs prefer to invest in later rounds when a technology is a safer prospect to get to market, forcing earlier-stage companies to look elsewhere for the money to fund their businesses.



## Annual VC Investments

Source: EvaluateMedTech™ July 2015



Realising that without investment the start-ups on which they depend for future technologies are imperilled, larger healthcare companies are filling at least part of the shortfall via their corporate VC arms. Novartis Venture Funds, for example, participated in Autonomic Technologies' \$38m round in May; Novartis might sell more drugs than any other pharma company, but it is also a major investor in early-stage medtechs.

Likewise crowdfunding is beginning to play a significant role in medtech. Scanadu, seventh place in the top-10 table by virtue of a \$35m round in April, obtained some of its initial funding via an Indiegogo campaign. The company is developing a scanner, the Scanadu Scout, designed to read a patient's vital signs and send them wirelessly to a smartphone. Showing a canny grasp of the kind of publicity crowdfunding demands, the company compares it with the fictional tricorder device from Star Trek.

Even so, the larger medtech companies and crowdfunding efforts cannot make up for the collapse in financing from dedicated VC funds. If this situation is not reversed the medtech industry could be heading for an "innovation crunch" – a catastrophic lack of new companies with new medical devices. VCs need to start spending and start spending now.



## Floats hold steady

The striking thing about the half-year figures for IPOs in the medtech sphere is the similarity they bear to those for the previous six-month period. The 14 device companies that have floated so far this year raised a total of \$705m – 3% less than the \$723m raised in the second half of 2014 – and the average amount raised was also almost identical, at \$54.2m.

While this half was almost a carbon-copy of the last, though, it is a huge drop from the first half of 2014, when the IPO window was open to its fullest extent. In that period 22 deals raised a total of \$1.5bn, and this remains an outlier.

While the IPO scene is quieter than it has been the window is still open – early 2015 saw more floats than all of 2013. It is crystal clear that venture cash is harder to come by than ever, so some companies might be forced to take the plunge onto the public markets earlier than they would like. And, as more of them try to get away while they can, they might have to take a haircut to do so.

There is a glimmer of hope for these firms in that bolt-on acquisitions are beginning to make a comeback, meaning that smaller device companies might be snapped up before they reach the point at which they consider a float. It could be that the plateauing means that the industry has found equilibrium.

Among the companies that did get away there is very nearly a tie for which takes first place in terms of cash raised. The molecular diagnostics group Biocartis just pips Glaukos, which makes a minute ocular stent to treat glaucoma, to the top spot with a haul of €100m (\$108.8m) compared with Glaukos's \$108.0m.

### Medtech IPOs since 2013

Source: EvaluateMedTech™ July 2015

	IPO count	Total raised (\$m)	Average raised (\$m)	Average discount/premium
H1 2013	6	150.0	25.0	(13%)
H2 2013	7	556.9	79.6	1%
H1 2014	22	1,504.7	68.4	(11%)
H2 2014	13	723.9	55.7	(9%)
H1 2015	14	704.6	54.2	(8%)

Of the two, however, Biocartis's is arguably the greater achievement given that the listing was European. The European markets tend to follow the IPO trends set by the US exchanges, but with fewer, smaller listings.

Biocartis's April IPO occurred before the current situation in Greece reached crisis point, and European stock markets were surprisingly stoic as the risk of a so-called Grexit grew, but even so Biocartis has done well.

This is surely partly to do with it being active in the still-hot area of molecular diagnostics used to identify drug responders. Investors clearly feel that, as a maker of high-margin products whose use is linked to the relatively buoyant biopharma sector, Biocartis has quite some potential – particularly considering that it is not yet selling its tests in the US.





## Top 5 medtech IPOs on US and pan-European stock exchanges in the first half of 2015

Source: EvaluateMedTech™ July 2015

Company	Area	Date	Amount raised	Offering price	Range	Discount/premium	Stock Exchange	Share price from float to June 30
Biocartis	In vitro diagnostics	27/04/15	€100m (\$109m)	€11.50	€10-€11.50	7%	Euronext Brussels	9%
Glaukos	Ophthalmics	25/06/15	\$108m	\$18	\$16-\$17	9%	NYSE	61%
Entellus Medical	Ear, nose & throat	29/01/15	\$78m	\$17	\$15-\$17	6%	Nasdaq	52%
Avinger	Cardiology	30/01/15	\$65m	\$13	\$12-\$14	0%	Nasdaq	(1%)
Carbylan Therapeutics	Drug delivery	9/04/15	\$65m	\$5	\$5	0%	Nasdaq	43%
<b>Average across all 13 IPOs</b>			<b>\$54m</b>			<b>(8%)</b>		<b>5%</b>



## Innovation key for share gains

For the first time in two years several large-cap companies saw their share prices decline in the first half. This, coupled with a slowdown in the US medtech stock indices, could be an indication that the recent boom times are coming to an end.

There were some positives to take away, however. The top big-cap risers were driven by approvals and successful launches of promising technologies, as well as smart deal-making. And there has also been a small improvement for the Thomson Reuters Europe Healthcare index in spite of the Eurozone crisis.

### Share price indices

Source: EvaluateMedTech™ July 2015

Stock index	% Change in 2015
Thomson Reuters Europe Healthcare (EU)	4%
Dow Jones U.S. Medical Equipment Index	5%
S&P Composite 1500 HealthCare Equipment & Supplies (US)	5%

While many of last year's best performers were bolstered by acquisitions, 2015 has seen different reasons for share price gains, with innovation chief among them. Specifically, FDA approval seemed to be a major catalyst for stock rises.

Boston Scientific, which tops the chart with 34% growth, bagged approval for its left atrial appendage closure device Watchman, and could see another boost if it gets reimbursement for the product – a decision is expected towards the end of this year or early 2016. Meanwhile, Edwards Lifesciences saw a late bump in its stock when its newest heart valve, Sapien 3, was granted premarket approval by the FDA in June.

Cardiology rival St. Jude Medical's CardioMEMS heart failure monitor might not be quite as new, but it was the subject of positive sentiment among analysts amid a better-than-expected first quarter that helped push up the company's share price. Some analysts have suggested that CardioMEMS could top \$1bn in peak sales.

Smith & Nephew's stock, however, performed badly in the first six months of 2015 as acquisition rumours subsided. The UK company has long been touted as a takeover target for Stryker, but the latter's \$2bn share buyback, announced in March, made this deal unlikely and sent S&N's stock into a tailspin.



## Large cap (\$15bn+) medtech companies: top risers and fallers in H1 2015

Source: EvaluateMedTech™ July 2015

Top five risers	Share price (local currency)			Market capitalisation (\$bn)	
	YE 2014	H1 2015	Change	H1 2015	6M change
Boston Scientific	\$13.25	\$17.70	34%	23.7	6.2
Essilor International	€92.68	€107.00	15%	25.0	0.5
St. Jude Medical	\$65.03	\$73.07	12%	20.5	1.9
Edwards Lifesciences	\$127.38	\$142.43	12%	15.3	1.7
Abbott Laboratories	\$45.02	\$49.08	9%	73.1	5.3
Top fallers					
Intuitive Surgical	\$528.94	\$484.50	(8%)	17.9	(1.3)
Smith & Nephew	\$36.74	\$33.95	(8%)	15.2	(1.7)
Baxter International	\$73.29	\$69.93	(5%)	38.0	(1.7)
Zimmer	\$113.42	\$109.23	(4%)	22.2	(3.0)

FDA approval was also a common theme among the mid and small-cap risers. Top of this list is the heart pump developer Abiomed, whose shares jumped 73% in the first six months of 2015 on the back of US approval of first its Impella RP temporary heart pump and then its flagship Impella 2.5 device. Combined, these could bring in peak sales of \$3bn a year, according to some of the more optimistic analysts.

Also getting a leg up from a new product was the glucose monitoring company DexCom, which bagged FDA clearance via the de novo route for the first apps to be regulated as medical devices. The Share Direct Secondary Displays permit carers and doctors to track a patient's blood sugar levels. Excitement over the much-vaunted artificial pancreas, a field in which DexCom is collaborating, has no doubt helped the company's stock more than double in the past 18 months.

Thanks to these approvals Abiomed and DexCom could both make attractive acquisition targets, which has doubtless spurred investors to get involved.

## Other significant risers and fallers in H1 2015 (ranked on market cap.)

Source: EvaluateMedTech™ July 2015

Top five risers	Share price (local currency)			Market capitalisation (\$m)	
	YE 2014	H1 2015	Change	H1 2015	6M change
Abiomed	\$38.06	\$65.73	73%	2,743	1,187
DexCom	\$55.05	\$79.98	45%	6,342	2,127
InVivo Therapeutics	\$1.32	\$16.15	206%	-	-
Iradimed	\$12.9	\$23.27	80%	255	116
IBA Group	€14.34	€24.42	70%	766	250
Top five fallers					
Sonova	SFr146.9	SFr126.4	(14%)	8,844	(1,500)
Coloplast	DKr465.9	DKr439.1	(6%)	12,843	(4,100)
OraSure Technologies	\$10.14	\$5.39	(47%)	304	(264)
Elekta	SKr79.7	SKr52	(35%)	2,219	(1,835)
OvaScience	\$44.22	\$28.93	(35%)	787	(289)



Among the mid-cap fallers, the hearing aid firm Sonova took a hit when the Swiss franc was unpegged from the euro. The company has also been hit by growing competition, which is partly linked to its decision to supply some products to the US chain Costco. Sonova lost share with independent suppliers, and the move also hit its US pricing power.

Coloplast also disappointed: it might pride itself on its patient-friendly approach, but its incontinence and wound care products are essentially generic. And the Danish company has not been helped by a whistleblower lawsuit in the US alleging improper sales practices and kickbacks to distributors as part of its Coloplast Care programme.

Meanwhile, the worst-performing small-cap company was the diagnostic specialist OraSure Technologies, whose share price almost halved as enthusiasm for its collaboration with AbbVie dissipated. AbbVie and OraSure have been co-promoting the latter's OraQuick HCV Rapid Test in the US but the larger company's efforts appear to have stalled, and the hepatitis C diagnostic had a rather slow sales ramp.



## FDA approvals show no sign of slowing

If medtech companies' share performance has been mixed the picture is much rosier when looking at the number and speed of FDA approvals. Indeed, 2015 could see the most device approvals for a decade if first-half figures are anything to go by.

Impressively, 26 devices were granted either a first-time premarket approval (PMA) or a humanitarian device exemption (HDE) during this period. If this rate is replicated over the rest of the year there will be 52 such approvals, compared with 33 during the whole of 2014 – and this was itself a 43% increase over 2013.

On one hand, this supports the view that the level of innovation is increasing – but on the other it could just be the case that getting products approved is becoming easier, or at least quicker.

And it is set to get faster still: in April, the FDA's expedited access PMA route became active, illustrating the agency's determination to speed up the regulatory process.

None of the devices that got the go-ahead so far this year can have been submitted via this route as their applications occurred before April.

**Number of PMAs and HDEs granted, 2005-2015**

Source: EvaluateMedTech™ July 2015







The average approval time in H1 2015 was 17.1 months compared with 16.7 months for the whole of 2014 – both much faster than the 26.9 months in 2013.

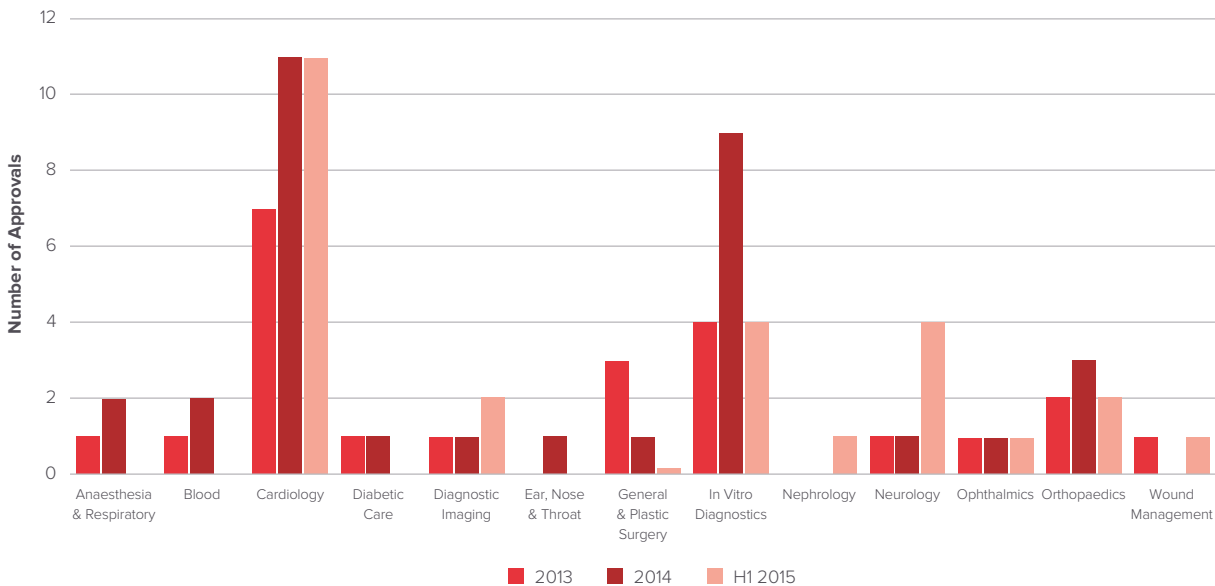
HDEs were, unsurprisingly, quicker than PMAs. Humanitarian device exemption is a rare disease approval; devices to treat conditions affecting fewer than 4,000 US patients can access this route. Kaneka's Lixelle, a blood filter used to treat a rare protein-folding condition associated with chronic kidney failure, took more than two years to gain its HDE, but Abiomed's Impella RP right-side heart pump got its HDE after just 4.4 months.

These were the only two HDEs in H1 2015, making the average time for these approvals 14.7 months, beating the 17.3 for PMAs alone.

The relatively low number of HDEs this year goes against the idea that the medtech industry might be targeting rare diseases with the same enthusiasm as the biopharma sector, as suggested after a rash of four HDEs in the second half of 2014. But, with a slightly lower burden of proof versus PMAs, this is still an attractive route for companies.

### First-time PMAs and HDEs by Therapy Area, 2013 to H1 2015

Source: EvaluateMedTech™ July 2015



Once again the sector seeing the most approvals was cardiology. There were 11 approvals for heart devices in H1 2015, the same number as seen in the whole of 2014.

And these approvals came relatively quickly: cardiology devices got the go-ahead in an average of 15.2 months, faster than the overall average of 17.1 months. Only imaging devices and products for wound management passed through the FDA more rapidly.



## Average review times for PMAs and HDEs by therapy area (months)

Source: EvaluateMedTech™ July 2015

EvaluateMedTech Device Classification - L1	2013	2014	H1 2015
Anaesthesia & respiratory	61.3	18.5	-
Blood	13.2	8.7	-
Cardiology	17.1	12.9	15.2
Diabetic care	15.7	19.0	-
Diagnostic imaging	16.8	13.0	11.5
Ear, nose & throat	-	9.5	-
General & plastic surgery	68.2	28.7	-
In vitro diagnostics	8.6	13.3	17.2
Nephrology	-	-	25.1
Neurology	40.5	8.9	18.4
Ophthalmics	21.4	11.0	28.1
Orthopaedics	30.0	48.0	21.7
Wound management	31.2	-	14.7
<b>Average</b>	<b>26.9</b>	<b>16.7</b>	<b>17.1</b>

There is an even faster route through which innovative devices can reach market in the US. Products that pose a low risk to patients can access the de novo 510(k) pathway.

The 10 devices granted de novo clearance in H1 got it in just less than a year on average.

The fastest de novo clearance went to the aforementioned DexCom Share Direct Secondary Displays apps, which got the green light after just 1.3 months. As healthcare apps become increasingly regulated we should see more approvals of this type.

Not everyone is happy about the FDA's efforts to streamline its processes. An op-ed in the *New York Times* on July 17 posited that proposed changes to US regulatory law could permit unsafe technologies onto the market thanks to a more relaxed attitude to clinical data.

In some ways, it seems that the agency cannot win: the US is widely believed to be more stringent than Europe in its assessment of medical devices, and efforts to tighten up European regulation have met with fierce resistance by industry lobbyists and patient groups.

Perhaps the two systems will eventually meet in the middle, spelling an end to the current state of affairs where, generally, medtech companies first seek CE mark for their devices in Europe, and then carry out more extensive clinical trials in order to get US approval.



## Calm, but too cool

The half-year point finds the medtech sector much changed from where it was a year or even six months ago, with some of the biggest names shifting to take a bigger share of the market and others moving out of it altogether. But the ructions are mostly over now, and the underlying signs are perhaps indicative of a more settled industry.

Since June there has been a sprinkling of M&A, including two megadeals: St. Jude has announced its intention to purchase the heart pump maker Thoratec for \$3.4bn and IBM is to acquire the imaging software company Merge Healthcare for \$1bn. Reassuringly, these are motivated more by technological considerations than simply bulking up for corporate purposes or to obtain lower tax rates.

There have been four medtech IPOs so far in the second half, and two, those of ConforMIS and Natera, have raised over \$100m. The markets are clearly still open to companies floating, and with the Greek Eurozone situation appearing to have been quelled, at least temporarily, perhaps there will be less risk in the coming months.

The venture funding scene, however, continues to be dismal in the extreme. True, there has finally been a standout VC funding, with Oxford Nanopore Technologies raking in \$109m for its DNA sequencing and molecular analysis systems. But this was a series H round, and the crisis affecting early-stage companies is undiminished.

With the huge and exciting changes that have gripped the industry over the past year having for the most part been brought to their respective conclusions, the sector seems to have attained a level of stability.

The headlines have been grabbed. Now it is time to take advantage of a calmer atmosphere to fix the single biggest problem threatening this space: closing the early-stage funding gap.

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