



EvaluateMedTech®

# World Preview 2016, Outlook to 2022

5th Edition – October 2016

 Evaluate®

# Welcome to the EvaluateMedTech® World Preview 2016, Outlook to 2022

Our fifth annual EvaluateMedTech® World Preview brings together many of our analyses to provide a top level insight into the expected performance of the medtech industry between now and 2022. Based on EvaluateMedTech®'s coverage of the world's leading medical device and diagnostic companies, the World Preview highlights trends in medtech including: consensus sales forecasts of leading industry analysts by device area to 2022; the top 20 companies in 2022; R&D spend current and future; FDA approvals; M&A; venture financing and IPOs. Complimentary copies of the full report can be downloaded at:

[www.evaluate.com/MedtechWorldPreview2016](http://www.evaluate.com/MedtechWorldPreview2016)

# About EvaluateMedTech®

EvaluateMedTech® provides trusted global medtech market intelligence and consensus forecasts delivered through a single integrated and standardised platform, that easily integrates with your own analytical models. It allows medtech companies, financial institutions, consultancies, service providers and others to efficiently track, benchmark and forecast the sector so more time can be spent examining insights and making effective decisions to optimise performance.

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# Foreword

In the 2016 edition of the EvaluateMedTech® World Preview we can reveal that the global medtech industry is expected to grow at 5.2% per year (CAGR) between 2015 and 2022, culminating in 2022 global sales of \$529.8bn (pages 8-9). The analysis is based on in-depth forecast models for the top 300 global medtech companies available within EvaluateMedTech®. This sales forecast represents the only current consensus view from equity analysts of the entire medtech market.

## **Diagnostics are big, but neurology is fast**

In vitro diagnostics will remain the number one device area in 2022 with sales of \$70.8bn – more than 13% of the industry's total sales. Roche is the leading company in this segment, with its 2022 test sales forecast to reach \$12.8bn.

IVDs may be the largest sector but it is not the fastest-growing. The greatest expansion of a top-15 device area will be seen in neurology, which has a forecast CAGR of 7.6% between 2015 and 2022. IVD sales will only grow at around 5.6% during this period.

## **Merger mania leaves Medtronic in charge**

Consolidation within the medtech industry is winding down, with M&A activity in the first half of this year having slumped 79% from the same period in 2015 to just \$17bn. Now the dust has settled Medtronic has emerged as the largest company by sales of medical devices: its 2015 revenues came to \$28.8bn. Remarkably, its 4.7% annual growth rate puts it even further ahead in 2022, when its medtech revenues are forecast to reach \$39.9bn.

That said, there are still a few sector-changing deals in the pipeline. Most notable is Abbott's pending purchase of St. Jude Medical for \$25bn which could help bump Abbott up the company rankings from seventh position overall to third.

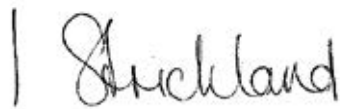
## **Ten-year approvals high**

On the regulatory front, the FDA has had an outstanding year, increasing the number of first-time PMAs and HDEs by 55% over 2014's total to a ten-year high of 51 in 2015.

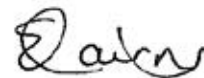
# Foreword

That said, the pace seems to have slowed slightly since. EvaluateMedTech® found that up to the end of August 2016, the FDA had issued 27 first-time PMAs, slightly down on the 2015 figure of 30 at this time point. As if to compensate, over the same period there were 15 de novo 510(k) clearances, a 50% increase over the same point last year.

Overall the device industry is growing reasonably rapidly, and the calming of the M&A scene is no bad thing. Already the sector is seeing a resurgence of smaller tuck-in deals on which start-ups, a significant source of disruptive new technologies, depend.



**Ian Strickland**  
Product Manager, EvaluateMedTech®



**Elizabeth Cairns**  
Medtech Reporter

# Analysis Highlights

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- Worldwide medtech sales forecast to reach \$529.8bn by 2022
  - Worldwide medtech market forecast to grow more slowly than prescription drug market, with a CAGR of 5.2% between 2015 and 2022 versus 6.1% for pharma
- 
- M&A activity in H1 2016 slumps 79% to \$17bn following 2015's flurry of mega mergers
  - Medtronic becomes the leading medtech company in 2015 following the \$50bn acquisition of Covidien
  - ...and Medtronic remains top in 2022; sales forecast to reach \$39.9bn
  - Johnson & Johnson retains leading position in the orthopedics market in 2022 with 24.1% market share; but Zimmer Biomet forecast to be a close 2nd with 20.6% market share
  - In vitro diagnostics remains number one device area in 2022 with sales of \$70.8bn; Roche continues domination of sector with 2022 sales forecast to reach \$12.8bn
  - Medtronic continues to dominate the cardiology market; sales forecast to reach \$14.1bn in 2022
  - Medtech R&D spend forecast to grow by 4.3% per annum to \$34.0bn in 2022
  - Medtronic tops table of R&D spenders in 2022 with \$2.8bn forecast
  - Number of first-time PMAs and HDEs hits a ten year high in 2015; 510(k) clearances decrease 6% to 3,064
  - Number of venture financing deals slumps 39% to 138 in H1 2016; value of venture financing only falls 6% to \$2.4bn
  - Medtech IPO deal values fall significantly in H1 2016 to \$164m

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# Worldwide Medtech Sales by Device Area in 2022



## Worldwide Medtech Sales Forecast to Reach \$529.8bn by 2022; IVD Remains Number One in 2022.

EvaluateMedTech® consensus forecasts find that the medtech market will achieve sales of \$529.8bn in 2022, growing by 5.2% per year (CAGR) between 2015 and 2022.

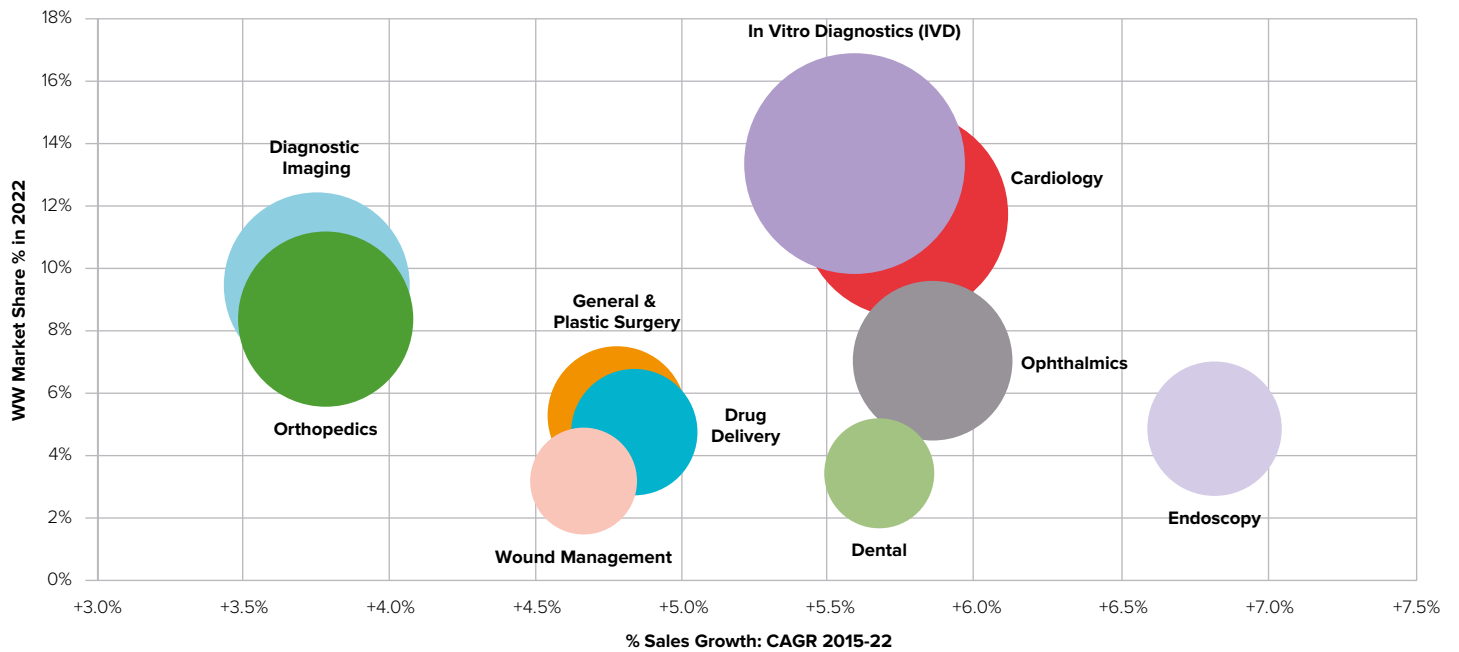
In vitro diagnostics (IVD) will be the largest device area in 2022, with sales forecast to reach \$70.8bn, representing 13.4% of the industry's

total sales. Cardiology takes the second spot, with annual sales increasing to \$62.3bn in 2022 from \$42.1bn in 2015.

Neurology is forecast to be the fastest-growing device area, with a CAGR of 7.6% between 2015 and 2022.

## Analysis on Top 10 Device Areas in 2022, Market Share & Sales Growth (2015-22)

Source: EvaluateMedTech® September 2016



Note: Size of Bubble = WW Sales in 2022





## WW Medtech Sales by EvaluateMedTech® Device Area: Top 15 Categories & Total Market (2015/22)

Source: EvaluateMedTech® September 2016

Rank	Device Area	WW Sales (\$bn)			WW Market Share			Rank Chg. (+/-)
		2015	2022	CAGR % Growth	2015	2022	Chg. (+/-)	
1.	In Vitro Diagnostics (IVD)	48.4	<b>70.8</b>	+5.6%	13.1%	13.4%	+0.3pp	-
2.	Cardiology	42.1	<b>62.3</b>	+5.7%	11.4%	11.8%	+0.4pp	-
3.	Diagnostic Imaging	38.9	<b>50.3</b>	+3.7%	10.5%	9.5%	-1.0pp	-
4.	Orthopedics	34.0	<b>44.1</b>	+3.8%	9.2%	8.3%	-0.8pp	-
5.	Ophthalmics	24.9	<b>37.1</b>	+5.8%	6.7%	7.0%	+0.3pp	-
6.	General & Plastic Surgery	20.2	<b>28.1</b>	+4.8%	5.5%	5.3%	-0.2pp	-
7.	Endoscopy	16.4	<b>26.0</b>	+6.8%	4.4%	4.9%	+0.5pp	+1
8.	Drug Delivery	17.6	<b>24.5</b>	+4.8%	4.8%	4.6%	-0.1pp	-1
9.	Dental	12.4	<b>18.3</b>	+5.7%	3.3%	3.4%	+0.1pp	-
10.	Wound Management	12.4	<b>17.0</b>	+4.7%	3.3%	3.2%	-0.1pp	-
11.	Diabetic Care	11.0	<b>16.2</b>	+5.7%	3.0%	3.1%	+0.1pp	-
12.	Nephrology	10.6	<b>15.4</b>	+5.5%	2.8%	2.9%	+0.1pp	-
13.	General Hospital & Healthcare Supply	10.3	<b>14.4</b>	+5.0%	2.8%	2.7%	-0.0pp	-
14.	Healthcare IT	7.8	<b>11.3</b>	+5.5%	2.1%	2.1%	+0.0pp	-
15.	Neurology	6.7	<b>11.1</b>	+7.6%	1.8%	2.1%	+0.3pp	+2
	<b>Top 15</b>	313.7	<b>446.8</b>	+5.2%	84.5%	84.3%	-0.2pp	
	<b>Other</b>	57.3	<b>83.0</b>	+5.4%	15.5%	15.7%	+0.2pp	
	<b>Total WW Medtech Sales</b>	<b>371.0</b>	<b>529.8</b>	+5.2%	100.0%	100.0%		

Note: Analysis is based on the top 300 medtech companies. Sales in 2015 based on company reported data. Sales forecasts to 2022 based on a consensus of leading equity analysts' estimates for segmental sales.

# Worldwide Medtech Sales in 2015: Top 20 Companies



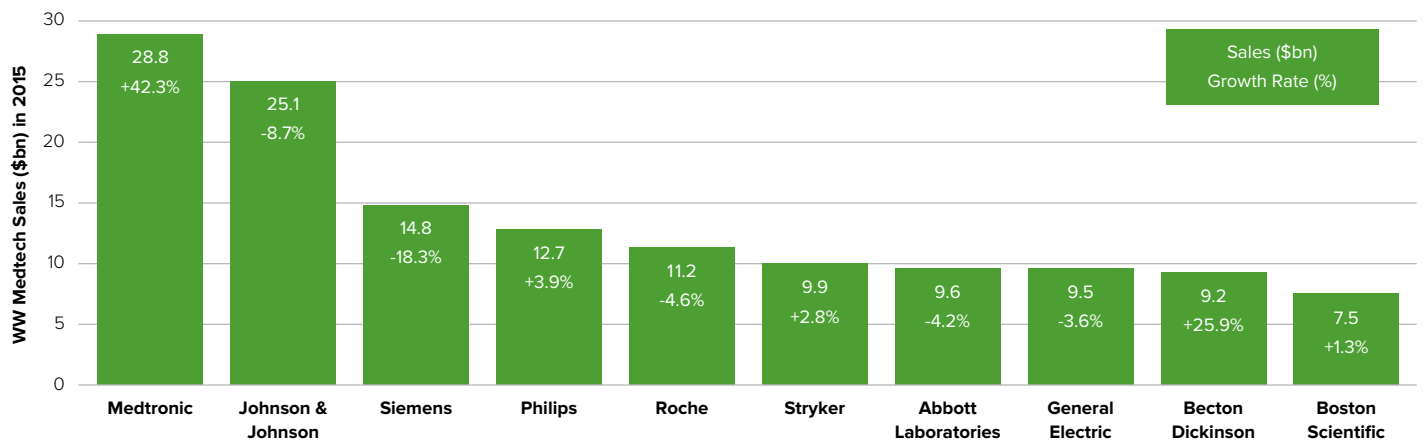
## Medtronic Becomes the Leading Medtech Company in 2015 Following the \$50bn Acquisition of Covidien.

EvaluateMedTech® finds that, thanks to its amalgamation with Covidien, Medtronic has leapfrogged Johnson & Johnson to become the world's leading medtech company in 2015. The company expanded by 42.3% from the previous year, reporting \$28.8bn in sales in 2015.

As expected, Becton Dickinson and Zimmer Biomet have also both experienced substantial growth following their mergers with CareFusion and Biomet, respectively. The past year has seen Stryker rise two places to become the sixth largest device maker, following a string of company acquisitions. Meanwhile, Siemens's medtech sales fell 18.3% to \$14.8bn following the disposal of their audiology and healthcare services divisions.

## WW Medtech Sales: Top 10 Companies (2015)

Source: EvaluateMedTech® September 2016



## WW Medtech Sales in 2015: Top 20 Companies & Total Market

Source: EvaluateMedTech® September 2016

Rank	Company	Country	WW Medtech Sales (\$bn)			WW Market Share			Rank Chg. (+/-)
			2014	2015	% Growth	2014	2015	Chg. (+/-)	
1.	Medtronic	USA	20.3	28.8	+42.3%	5.3%	7.8%	+2.4pp	+1
2.	Johnson & Johnson	USA	27.5	25.1	-8.7%	7.3%	6.8%	-0.5pp	-1
3.	Siemens	Germany	18.2	14.8	-18.3%	4.8%	4.0%	-0.8pp	-
4.	Philips	The Netherlands	12.2	12.7	+3.9%	3.2%	3.4%	+0.2pp	-
5.	Roche	Switzerland	11.8	11.2	-4.6%	3.1%	3.0%	-0.1pp	-
6.	Stryker	USA	9.7	9.9	+2.8%	2.6%	2.7%	+0.1pp	+2
7.	Abbott Laboratories	USA	10.0	9.6	-4.2%	2.6%	2.6%	-0.1pp	-1
8.	General Electric	USA	9.8	9.5	-3.6%	2.6%	2.6%	-0.0pp	-1
9.	Becton Dickinson	USA	7.3	9.2	+25.9%	1.9%	2.5%	+0.5pp	+1
10.	Boston Scientific	USA	7.4	7.5	+1.3%	1.9%	2.0%	+0.1pp	-1
11.	Danaher	USA	6.7	7.4	+9.4%	1.8%	2.0%	+0.2pp	+2
12.	B. Braun Melsungen	Germany	7.2	6.8	-5.7%	1.9%	1.8%	-0.1pp	-1
13.	Baxter International	USA	7.0	6.6	-5.9%	1.9%	1.8%	-0.1pp	-1
14.	Essilor International	France	6.6	6.5	-1.9%	1.7%	1.7%	+0.0pp	+1
15.	Novartis	Switzerland	6.6	6.0	-9.3%	1.7%	1.6%	-0.1pp	-1

Top 16-20 continued over...

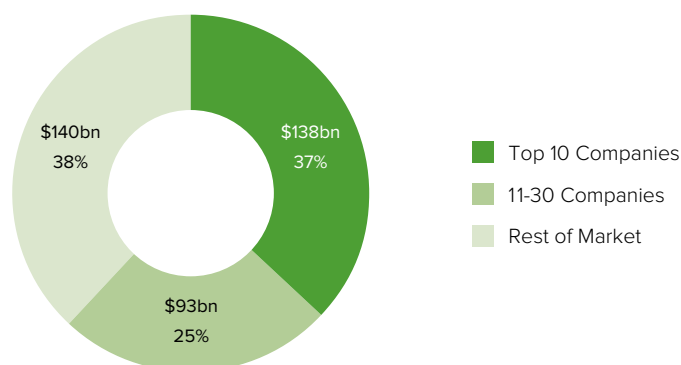


Source: EvaluateMedTech® September 2016

Rank	Company	Country	WW Medtech Sales (\$bn)			WW Market Share			Rank
			2014	2015	% Growth	2014	2015	Chg. (+/-)	Chg. (+/-)
16.	<b>Zimmer Biomet</b>	USA	4.7	<b>6.0</b>	+28.3%	1.2%	1.6%	+0.4pp	+3
17.	<b>St. Jude Medical</b>	USA	5.6	<b>5.5</b>	-1.4%	1.5%	1.5%	+0.0pp	-1
18.	<b>3M</b>	USA	5.3	<b>5.1</b>	-4.7%	1.4%	1.4%	-0.0pp	-1
19.	<b>Olympus</b>	Japan	5.1	<b>5.1</b>	-0.5%	1.3%	1.4%	+0.0pp	-1
20.	<b>Smith &amp; Nephew</b>	United Kingdom	4.6	<b>4.6</b>	+0.4%	1.2%	1.2%	+0.0pp	+1
<b>Total Top 20</b>			193.7	<b>198.0</b>	+2.2%	51.1%	53.4%	+2.2pp	
<b>Other</b>			185.0	<b>173.0</b>	-6.5%	48.9%	46.6%	-2.2pp	
<b>Total</b>			378.7	<b>371.0</b>	-2.0%	100.0%	100.0%		

## Percentage Composition of WW Medtech Market in 2015

Source: EvaluateMedTech® September 2016



Note: Analysis is based on the top 300 medtech companies. Sales based on company reported data.

# Worldwide Medtech Sales in 2022: Top 20 Companies



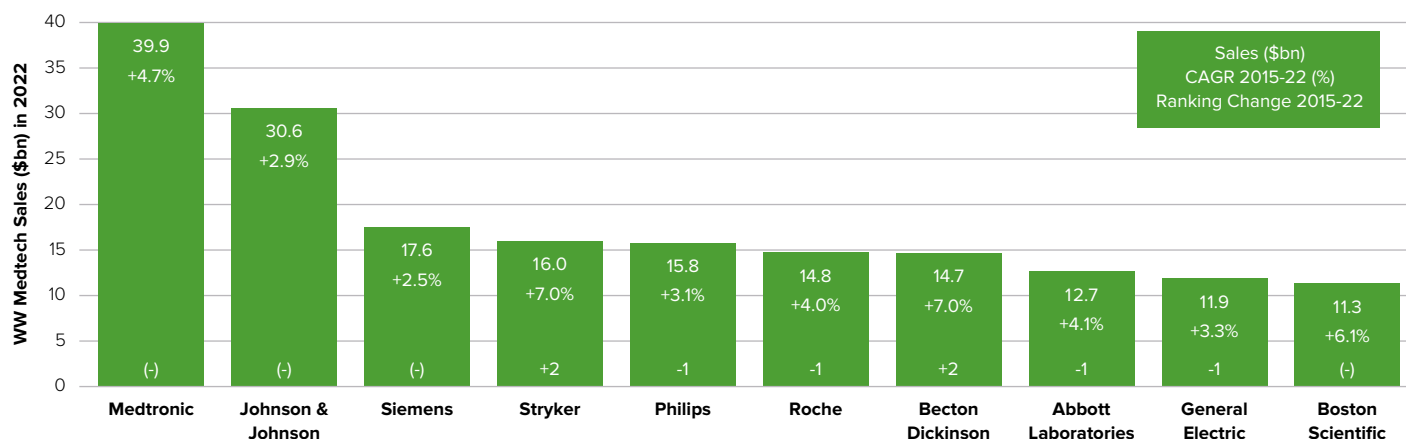
## Medtronic Remains Top Medtech Company in 2022; Sales Forecast to Reach \$39.9bn.

EvaluateMedTech® and EvaluatePharma® consensus forecasts find that Medtronic will remain the world's leading company in 2022. It is forecast to achieve sales of \$39.9bn, representing a 7.5% share of the medical device market.

Abbott Laboratories has announced several M&A deals this year. It is currently in the process of acquiring both St. Jude Medical and Alere and is also selling its eyecare business to Johnson & Johnson. Following the completion of these deals the company ought to jump from 7th in 2015 to 3rd place in 2022 in the company rankings, with potential sales of around \$22bn in 2022.

## WW Medtech Sales: Top 10 Companies (2022)

Source: EvaluateMedTech® September 2016



## WW Medtech Sales: Top 20 Companies & Total Market (2015/22)

Source: EvaluateMedTech® September 2016

Rank	Company	Country	WW Medtech Sales (\$bn)			WW Market Share			Rank Chg. (+/-)
			2015	2022	% CAGR 15-22	2015	2022	Chg. (+/-)	
1.	Medtronic	USA	28.8	39.9	+4.7%	7.8%	7.5%	-0.2pp	-
2.	Johnson & Johnson	USA	25.1	30.6	+2.9%	6.8%	5.8%	-1.0pp	-
3.	Siemens	Germany	14.8	17.6	+2.5%	4.0%	3.3%	-0.7pp	-
4.	Stryker	USA	9.9	16.0	+7.0%	2.7%	3.0%	+0.3pp	+2
5.	Philips	The Netherlands	12.7	15.8	+3.1%	3.4%	3.0%	-0.4pp	-1
6.	Roche	Switzerland	11.2	14.8	+4.0%	3.0%	2.8%	-0.2pp	-1
7.	Becton Dickinson	USA	9.2	14.7	+7.0%	2.5%	2.8%	+0.3pp	+2
8.	Abbott Laboratories	USA	9.6	12.7	+4.1%	2.6%	2.4%	-0.2pp	-1
9.	General Electric	USA	9.5	11.9	+3.3%	2.6%	2.3%	-0.3pp	-1
10.	Boston Scientific	USA	7.5	11.3	+6.1%	2.0%	2.1%	+0.1pp	-
11.	Essilor International	France	6.5	10.2	+6.7%	1.7%	1.9%	+0.2pp	+3
12.	Zimmer Biomet	USA	6.0	9.6	+7.0%	1.6%	1.8%	+0.2pp	+4
13.	Danaher	USA	7.4	9.1	+3.0%	2.0%	1.7%	-0.3pp	-2
14.	B. Braun Melsungen	Germany	6.8	8.8	+3.8%	1.8%	1.7%	-0.2pp	-2
15.	Baxter International	USA	6.6	8.7	+4.0%	1.8%	1.6%	-0.1pp	-2

Top 16-20 continued over...

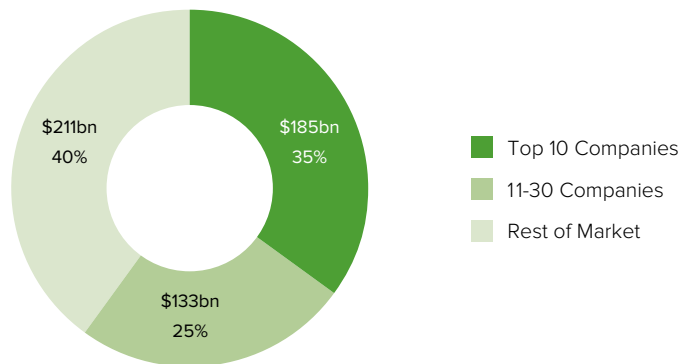


Source: EvaluateMedTech® September 2016

Rank	Company	Country	WW Medtech Sales (\$bn)			WW Market Share			Rank
			2015	2022	% CAGR 15-22	2015	2022	Chg. (+/-)	Chg. (+/-)
16.	<b>Olympus</b>	Japan	5.1	<b>8.2</b>	+7.1%	1.4%	1.6%	+0.2pp	+3
17.	<b>Novartis</b>	Switzerland	6.0	<b>7.9</b>	+4.0%	1.6%	1.5%	-0.1pp	-2
18.	<b>St. Jude Medical</b>	USA	5.5	<b>7.7</b>	+4.8%	1.5%	1.5%	-0.0pp	-1
19.	<b>3M</b>	USA	5.1	<b>6.8</b>	+4.2%	1.4%	1.3%	-0.1pp	-1
20.	<b>Smith &amp; Nephew</b>	United Kingdom	4.6	<b>6.1</b>	+4.1%	1.2%	1.2%	-0.1pp	-
<b>Total Top 20</b>			198.0	<b>268.5</b>	+4.4%	53.4%	50.7%	-2.7pp	
<b>Other</b>			173.0	<b>261.3</b>	+6.1%	46.6%	49.3%	+2.7pp	
<b>Total</b>			371.0	<b>529.8</b>	+5.2%	100.0%	100.0%		

## Percentage Composition of WW Medtech Market in 2022

Source: EvaluateMedTech® September 2016



Note: Analysis is based on the top 300 medtech companies. Sales in 2015 based on company reported data. Sales forecasts to 2022 based on a consensus of leading equity analysts' estimates for segmental sales.

# Worldwide Medtech vs. Prescription Drug Sales (2009-22)



## Worldwide Prescription Drug Market Continues to Outperform the Medtech Market.

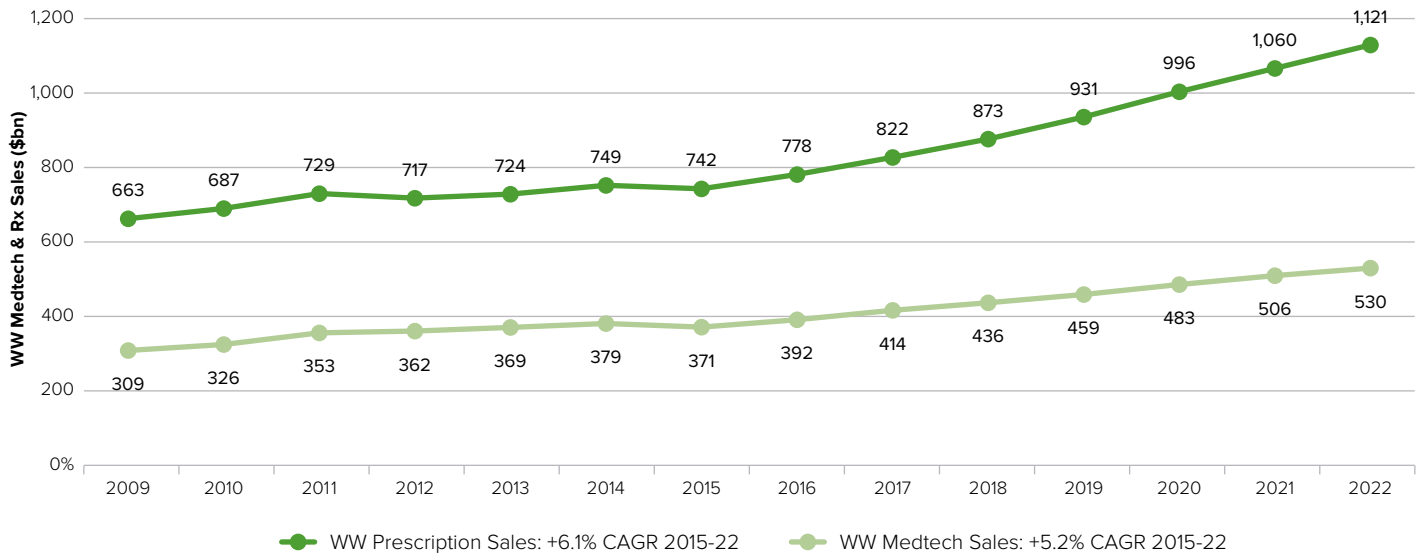
EvaluateMedTech® and EvaluatePharma® consensus forecasts find that the medtech market is forecast to grow at 5.2% per annum (CAGR) to reach \$530bn by 2022. By comparison, the worldwide prescription drug market is forecast to grow by 6.1% per year from 2015, reaching \$1,121bn by 2022. Both industries are expected to experience steady upward growth over the coming seven years.

This slower growth in medical device sales means the value of the medtech market will be around 47.3% of that of the prescription drug market in 2022. The medtech sector was half the size of the prescription drug market in 2015.

Both industries contracted in dollar terms in 2015 as a result of the weakness in the Euro, as US companies recognised fewer dollars for sales in the Eurozone.

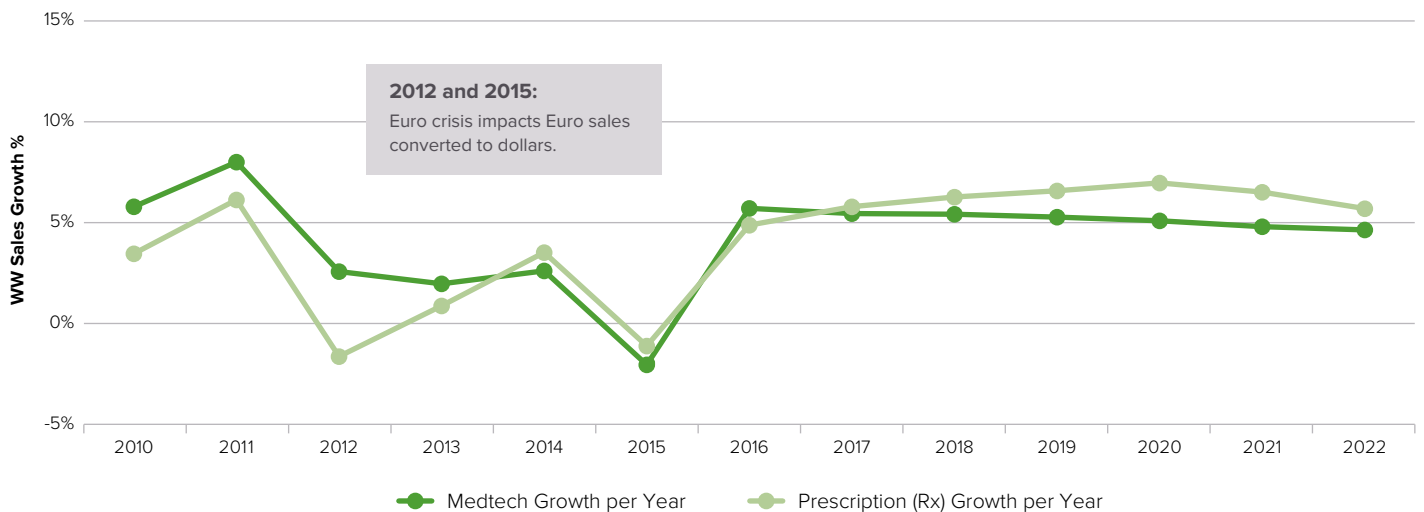
## WW Medtech vs Prescription Drug Sales (2009-22)

Source: EvaluateMedTech® & EvaluatePharma® September 2016



## WW Growth Rate: Medtech vs. Prescription Drug Sales (2010-22)

Source: EvaluateMedTech® & EvaluatePharma® September 2016





## WW Medtech vs. Prescription Drug Sales (2009-22)

Source: EvaluateMedTech\* &amp; EvaluatePharma\* September 2016

Year	WW Sales (\$bn)													
	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
WW Medtech Sales	309	326	353	362	369	379	371	392	414	436	459	483	506	530
Growth per Year		+5.7%	+8.0%	+2.6%	+2.0%	+2.7%	-2.0%	+5.7%	+5.4%	+5.5%	+5.3%	+5.1%	+4.9%	+4.7%
Medtech as % of Rx	46.5%	47.5%	48.4%	50.4%	51.0%	50.6%	50.0%	50.4%	50.3%	49.9%	49.3%	48.5%	47.7%	47.3%
WW Prescription (Rx)	663	687	729	717	724	749	742	778	822	873	931	996	1,060	1,121
Growth per Year		+3.5%	+6.1%	-1.6%	+0.9%	+3.5%	-1.0%	+4.8%	+5.7%	+6.2%	+6.6%	+7.0%	+6.5%	+5.7%

### CAGR 2015-22

WW Medtech Sales +5.2%

WW Prescription Drug Sales +6.1%

Note: Prescription drug sales based on top 500 pharmaceutical and biotech companies from EvaluatePharma\*. Sales to 2015 based on company reported sales data. Sales forecasts to 2022 based on a consensus of leading equity analysts' estimates for segmental sales.

# Worldwide Medtech R&D Spend (2009-22)



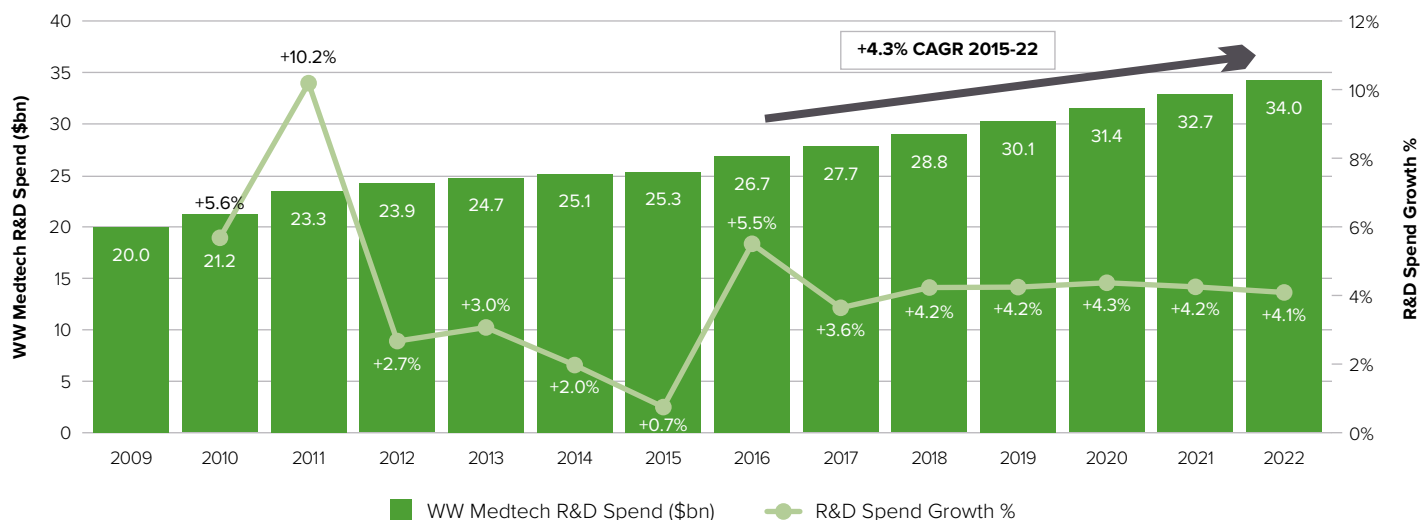
## Medtech R&D Spend Forecast to Grow by 4.3% Per Annum to \$34.0bn in 2022.

EvaluateMedTech® consensus forecasts find that worldwide, medtech R&D spending is expected to grow by 4.3% (CAGR) per year between

2015 and 2022, when it will reach \$34.0bn. The R&D investment rate as a percentage of sales is forecast to decline slightly from 6.8% in 2015 to 6.4% in 2022.

## WW Medtech R&D Spend (2009-22)

Source: EvaluateMedTech® September 2016



## WW Medtech R&D Spend (2009-22)

Source: EvaluateMedTech® September 2016

Year	WW Medtech R&D & Medtech Sales (\$bn)													
	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Medtech R&D Spend	20.0	21.2	23.3	23.9	24.7	25.1	25.3	26.7	27.7	28.8	30.1	31.4	32.7	34.0
R&D Spend Growth per Year %		+5.6%	+10.2%	+2.7%	+3.0%	+2.0%	+0.7%	+5.5%	+3.6%	+4.2%	+4.2%	+4.3%	+4.2%	+4.1%
WW Medtech Sales	308.6	326.3	352.6	361.6	368.8	378.7	371.0	392.2	413.6	436.3	459.4	482.7	506.2	529.8
R&D as % of Medtech Sales	+6.5%	+6.5%	+6.6%	+6.6%	+6.7%	+6.6%	+6.8%	+6.8%	+6.7%	+6.6%	+6.5%	+6.5%	+6.5%	+6.4%
R&D as % of Medtech Sales (Top 20 in 2022)							8.4%							8.0%

CAGR 2015-22 on Medtech R&D Spend +4.3%  
 Cumulative 5 year R&D Spend (2011-15) \$122.3bn  
 CAGR 2009-15 on Medtech R&D Spend +4.0%

Note: Analysis is based on the Top 300 medtech companies. R&D spend in 2015 based on company reported data.

Forecast medtech R&D spend based on a consensus of leading equity analysts' estimates for company level R&D spend, extrapolated to medtech R&D when a company has non-medtech R&D activity.

Medtech R&D is not disclosed by a number of companies and this analysis is limited to those companies with sufficient disclosure.



# Medtech R&D Spend in 2022: Top 20 Companies



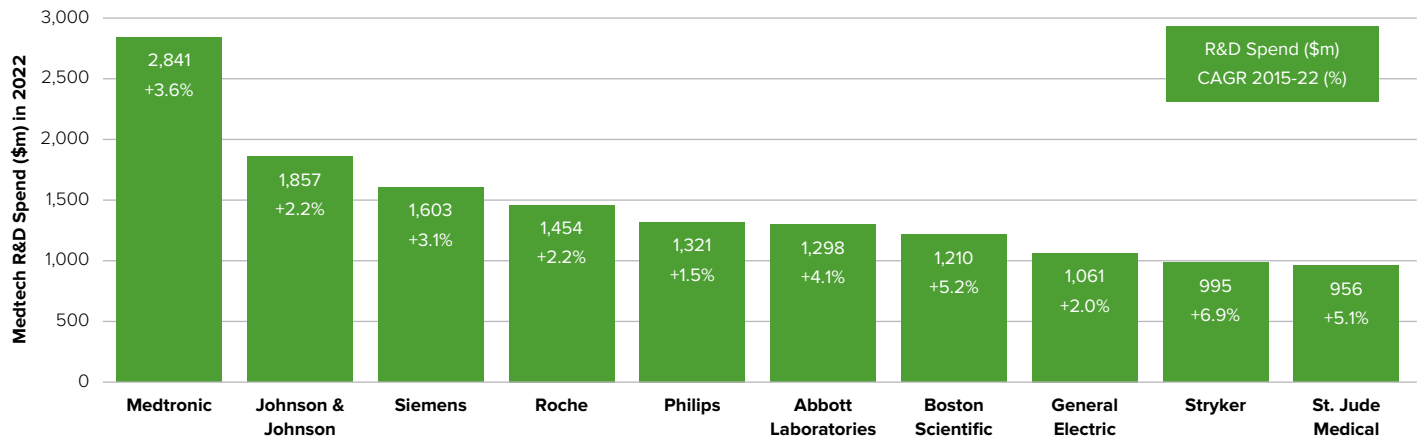
## Medtronic Tops Table of R&D Spenders in 2022 with \$2.8bn Forecast.

Medtronic will allocate \$2.8bn to R&D in 2022, making it the sector's biggest research spender. Its R&D expenditure will increase at a CAGR of 3.6% between 2015 and 2022. It does not, however, spend

the most proportionally to total medtech sales – that title belongs to Edwards Lifesciences with an estimated 15.0% R&D investment rate in 2022. This contrasts with Zimmer Biomet, which will reinvest a mere 4.8% of its total medtech sales in research.

## WW Medtech R&D Spend: Top 10 Companies (2022)

Source: EvaluateMedTech® September 2016



## WW Medtech R&D Spend: Top 20 Companies & Total Market (2015/22)

Source: EvaluateMedTech® September 2016

Rank	Company	Medtech R&D (\$m)			R&D As a % of Medtech Sales			Rank Chg. (+/-)
		2015	2022	CAGR 15-22	2015	2022	Chg. (+/-)	
1.	Medtronic	2,224	<b>2,841</b>	+3.6%	7.7%	7.1%	-0.6pp	-
2.	Johnson & Johnson	1,600	<b>1,857</b>	+2.2%	6.4%	6.1%	-0.3pp	-
3.	Siemens	1,294	<b>1,603</b>	+3.1%	8.7%	9.1%	+0.4pp	-
4.	Roche	1,245	<b>1,454</b>	+2.2%	11.1%	9.9%	-1.2pp	-
5.	Philips	1,190	<b>1,321</b>	+1.5%	9.4%	8.4%	-1.0pp	-
6.	Abbott Laboratories	977	<b>1,298</b>	+4.1%	10.1%	10.1%	+0.1pp	-
7.	Boston Scientific	850	<b>1,210</b>	+5.2%	11.4%	10.7%	-0.7pp	+1
8.	General Electric	926	<b>1,061</b>	+2.0%	9.8%	8.9%	-0.9pp	-1
9.	Stryker	625	<b>995</b>	+6.9%	6.3%	6.2%	-0.1pp	+3
10.	St. Jude Medical	676	<b>956</b>	+5.1%	12.2%	12.4%	+0.2pp	-
11.	Danaher	688	<b>902</b>	+3.9%	9.3%	10.0%	+0.6pp	-2
12.	Becton Dickinson	632	<b>872</b>	+4.7%	6.9%	5.9%	-1.0pp	-1
13.	Baxter International	589	<b>694</b>	+2.4%	8.9%	8.0%	-0.9pp	-
14.	Edwards Lifesciences	383	<b>692</b>	+8.8%	15.4%	15.0%	-0.3pp	+2
15.	3M	434	<b>580</b>	+4.2%	8.5%	8.5%	-0.0pp	-

Top 16-20 continued over...



Source: EvaluateMedTech® September 2016

Rank	Company	Medtech R&D (\$m)			R&D As a % of Medtech Sales			Rank
		2015	2022	CAGR 15-22	2015	2022	Chg. (+/-)	Chg. (+/-)
16.	<b>Novartis</b>	451	<b>488</b>	+1.1%	7.5%	6.2%	-1.3pp	-2
17.	<b>Zimmer Biomet</b>	269	<b>460</b>	+8.0%	4.5%	4.8%	+0.3pp	+3
18.	<b>Olympus</b>	279	<b>433</b>	+6.5%	5.5%	5.3%	-0.2pp	-
19.	<b>Terumo</b>	276	<b>421</b>	+6.2%	7.1%	7.0%	-0.1pp	-
20.	<b>bioMérieux</b>	265	<b>382</b>	+5.4%	15.3%	14.1%	-1.3pp	+1
	<b>Total Top 20</b>	15,873	<b>20,519</b>	+3.7%	8.4%	8.0%	-0.4pp	
	<b>Other</b>	9,447	<b>13,514</b>	+5.2%				
	<b>Total</b>	<b>25,320</b>	<b>34,033</b>	+4.3%	<b>6.8%</b>	<b>6.4%</b>		

Note: Analysis is based on the top 300 medtech companies. R&D spend in 2015 based on company reported data.

Forecast medtech R&D spend based on a consensus of leading equity analysts' estimates for company level R&D spend, extrapolated to medtech R&D when a company has non-medtech R&D activity.

Medtech R&D is not disclosed by a number of companies and this analysis is limited to those companies with sufficient disclosure.



## Number of First-Time PMAs and HDEs hits a Ten Year High in 2015; 510(k) Clearances Decrease 6% to 3,064.

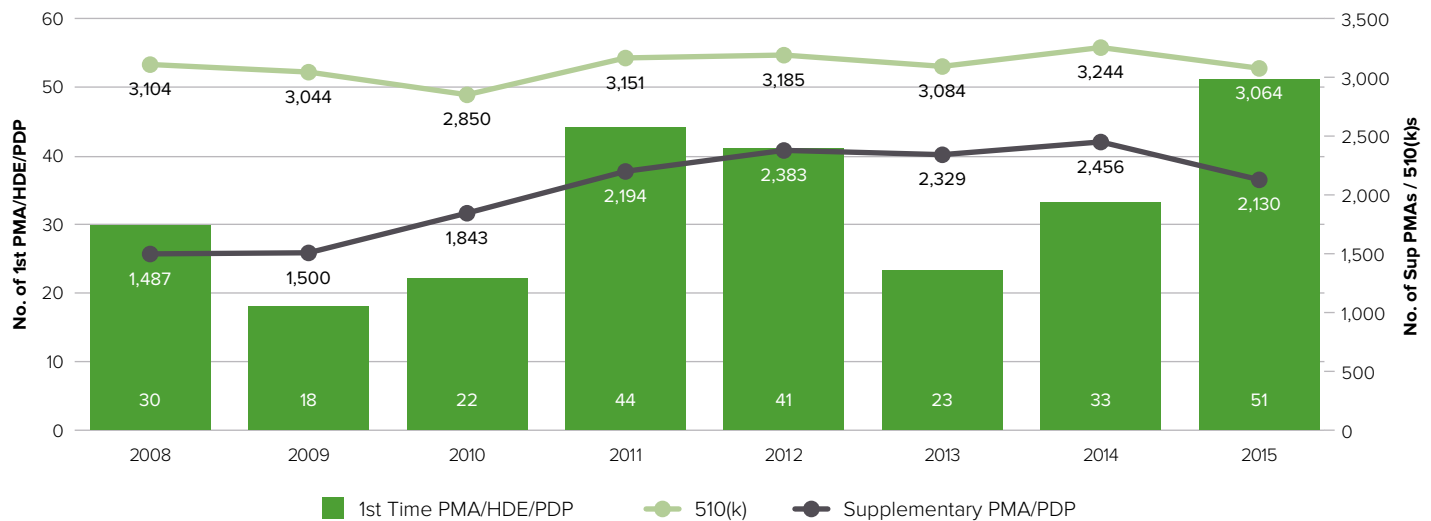
EvaluateMedTech® found that the FDA granted 51 new PMAs/HDEs/PDPs (first-time approvals) in 2015, a 55% increase over 2014's total. Roche was awarded more first-time PMAs than any other company,

with six of its tests receiving the green light. Medtronic received the largest number of overall approvals plus clearances in 2015, with 711.

The total number of regulatory approvals in 2015 decreased 9% from the year before.

## Count of 1st PMA/HDE/PDPs, 510(k)s & Supplementary PMA/PDPs Per Year (2008-15)

Source: EvaluateMedTech® September 2016



## Count of 1st PMA/HDE/PDPs, 510(k)s & Supplementary PMA/PDPs (2008-15)

Source: EvaluateMedTech® September 2016

Year	2008	2009	2010	2011	2012	2013	2014	2015
1st Time PMA/ HDE/ PDP	30	18	22	44	41	23	33	51
% Chg.		-40%	+22%	+100%	-7%	-44%	+43%	+55%
Supplementary PMA/ PDP	1,487	1,500	1,843	2,194	2,383	2,329	2,456	2,130
% Chg.		+1%	+23%	+19%	+9%	-2%	+5%	-13%
510(k)	3,104	3,044	2,850	3,151	3,185	3,084	3,244	3,064
% Chg.		-2%	-6%	+11%	+1%	-3%	+5%	-6%
<b>Total</b>	<b>4,621</b>	<b>4,562</b>	<b>4,715</b>	<b>5,389</b>	<b>5,609</b>	<b>5,436</b>	<b>5,733</b>	<b>5,245</b>
% Chg.		-1%	+3%	+14%	+4%	-3%	+5%	-9%



**Count of PMA/HDE/PDPs, 510(k)s & Medtech R&D Spend (2015)**

Source: EvaluateMedTech® September 2016

Rank	Company	PMA/HDEs - First Approval	PMA/PDPs - Suppl.	510(k) Clearance	Total Approvals	2015 R&D Spend (\$m)
1.	<b>Medtronic</b>	4	610	97	711	2,224
2.	<b>Boston Scientific</b>	3	272	27	302	850
3.	<b>St. Jude Medical</b>	1	155	10	166	676
4.	<b>Johnson &amp; Johnson</b>	0	110	46	156	1,600
5.	<b>Zimmer Biomet</b>	0	29	65	94	269
6.	<b>Abbott Laboratories</b>	0	71	18	89	977
7.	<b>Roche</b>	6	57	13	76	1,245
8.	<b>Siemens</b>	2	14	50	66	1,294
9.	<b>Stryker</b>	0	4	56	60	625
10.	<b>W. L. Gore &amp; Associates</b>	0	58	2	60	n/a
<b>Total</b>		<b>51</b>	<b>2,130</b>	<b>3,064</b>	<b>5,245</b>	

Note: Based on Devices@FDA data.

PMA (Premarket Approval): a class III device which is a 'life-sustaining or life-supporting implantable device'; usually require trials.

510(k): "substantially equivalent" to a legally marketed Class I, II, III device (where PMA not required).

HDE (Humanitarian Device Exemption): a device for treating or diagnosing a disease/condition that affects <4,000 individuals in the US per year.

Note: W. L. Gore & Associates R&D spend is not disclosed.

# 2016 FDA First-Time PMAs, HDEs and 510(k) De Novo Clearances



## Approval Rate for First-time PMAs Holds Steady in the First Eight Months of 2016 with Cardiology Continuing to Stand Out.

EvaluateMedTech® found that up to the end of August 2016, the FDA had issued 27 first-time PMAs, only slightly down on the 2015 figure of 30. The therapy area that saw most approvals was cardiology: 11 heart devices were granted PMAs.

Over the same period there were 15 de novo 510(k) clearances, a 50% increase over the same point last year.

At the time of publication there were no first-time HDE approvals listed on the FDA website. In the first eight months of last year there were three.

## 2016 FDA First-Time PMAs (to 31 August 2016)

Source: EvaluateMedTech® September 2016

EvaluateMedTech® Device Classification							
Level 1	Level 2	Level 3	Decision Date	FDA Review Time (mths)	Company	Product Code Name	Device Name (Approval Code)
Cardiology	Cardiac Prosthetic Devices	Tissue Heart Valves	12 Aug 16	10.0	Edwards Lifesciences	Heart-Valve, Non-Allograft Tissue	EDWARDS INTUITY ELITE VALVE SYSTEM (P150036)
Cardiology	Cardiac Prosthetic Devices	Tissue Heart Valves	08 Jan 16	10.3	LivaNova	Heart-Valve, Non-Allograft Tissue	PERCEVAL SUTURELESS HEART VALVE (P150011)
Cardiology	Cardiac Rhythm Management (CRM)	Pacemakers	25 Apr 16	13.8	Boston Scientific	Implantable Pulse Generator, Pacemaker (Non-Crt)	IMAGEREADY MR CONDITIONAL PACING SYSTEM AND INGEVITY PACE/SENSE LEAD (P150012)
Cardiology	Cardiac Rhythm Management (CRM)	Pacemakers	06 Apr 16	6.6	Medtronic	Leadless Pacemaker	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM (P150033)
Cardiology	Cardiovascular Surgical Devices	Vascular Closure Devices	20 Jul 16	17.5	Vasorum	Device, Hemostasis, Vascular	CELT ACD VASCULAR CLOSURE DEVICE (P150006)
Cardiology	Cardiovascular Surgical Devices	Vascular Closure Devices	12 Feb 16	7.6	Rex Medical	Device, Hemostasis, Vascular	CLOSER VASCULAR SEALING SYSTEM (P150022)
Cardiology	Electrophysiology	Cardiac Ablation Catheters	01 Apr 16	8.1	CardioFocus	Catheter, Percutaneous, Cardiac Ablation, For Treatment Of Atrial Fibrillation	HEARTLIGHT ENDOSCOPIC ABLATION SYSTEM (P150026)
Cardiology	Electrophysiology	Cardiac Ablation Catheters	24 Feb 16	12.7	Boston Scientific	Catheter, Percutaneous, Cardiac Ablation, For Treatment Of Atrial Flutter	BLAZER OPEN-IRRIGATED ABLATION CATHETER (P150005)
Cardiology	Interventional Cardiology	Drug-Eluting Coronary Stents	05 Jul 16	12.2	Abbott Laboratories	Absorbable Coronary Drug-Eluting Stent	ABSORB GT1 BIORESORBABLE VASCULAR SCAFFOLD (BVS) SYSTEM (P150023)
Cardiology	Interventional Cardiology	Non-Drug-Eluting Coronary Stents	25 Mar 16	7.7	NuMED	Aortic Stent	CHEATHAM PLATINUM STENT SYSTEM (P150028)
Cardiology	Interventional Cardiology	Peripheral Vascular Devices	27 Jul 16	5.8	W. L. Gore & Associates	Stent, Superficial Femoral Artery	GORE TIGRIS VASCULAR STENT (P160004)
Diabetic Care	Glucose Monitoring Devices	Glucose Test Systems	17 Jun 16	10.3	Medtronic	Sensor, Glucose, Invasive	IPO2 CGM SYSTEM WITH ENLITE SENSOR (P150029)
Diabetic Care	Insulin Delivery Devices	Artificial Pancreas	10 Aug 16	19.1	Medtronic	Artificial Pancreas Device System, Threshold Suspend	MINIMED 630G SYSTEM WITH SMARTGUARD (P150001)
Gastro-enterology	Gastrointestinal Therapeutic Devices	Other Gastrointestinal Therapeutic Devices	14 Jun 16	11.2	Aspire Bariatrics	Aspiration Therapy System	ASPIREASSIST (P150024)
General Hospital & Healthcare Supply	Other General Hospital Supplies	Other General Hospital Supplies	17 Feb 16	39.8	Sharps Terminator	Device, Needle Destruction	SHARPS TERMINATOR (P120018)

continued over...



## 2016 FDA First-Time PMAs (to 31 August 2016) contd.

Source: EvaluateMedTech® September 2016

EvaluateMedTech® Device Classification							
Level 1	Level 2	Level 3	Decision Date	FDA Review Time (mths)	Company	Product Code Name	Device Name (Approval Code)
In Vitro Diagnostics (IVD)	Histology & Cytology	Immunohistochemistry	18 May 16	4.1	Roche	Immunohistochemistry Assay, Antibody, Programmed Death-Ligand 1	VENTANA PD-L1(SP142) CDX ASSAY (P160002)
In Vitro Diagnostics (IVD)	Histology & Cytology	Immunohistochemistry	23 Jan 16	5.7	Agilent Technologies	Immunohistochemistry Assay, Antibody, Programmed Death-Ligand 1	PD-L1 IHC NIVOLUMAB PHARMDX (P150027)
In Vitro Diagnostics (IVD)	Molecular Diagnostics	Oncology Molecular Diagnostics	01 Jun 16	5.8	Roche	Somatic Gene Mutation Detection System	COBAS EGFR MUTATION TEST V2 (P150047)
In Vitro Diagnostics (IVD)	Molecular Diagnostics	Oncology Molecular Diagnostics	12 Apr 16	39.3	Epigenomics	System, Colorectal Neoplasia, Dna Methylation And Hemoglobin Detection	EPI PROCOLON (P130001)
In Vitro Diagnostics (IVD)	Molecular Diagnostics	Oncology Molecular Diagnostics	11 Apr 16	5.4	Abbott Laboratories	Fluorescence In Situ Hybridization, Chromosome 17p Deletion (Tp53)	VYSIS CLL FISH PROBE KIT (P150041)
Neurology	Neurology Therapeutic Devices	Other Neurology Therapeutic Devices	11 Jul 16	8.7	Elbit Imaging	Mr-Guided Focused Ultrasound System	EXABLATE (P150038)
Neurology	Neurology Therapeutic Devices	Other Neurology Therapeutic Devices	11 Feb 16	12.4	St. Jude Medical	Dorsal Root Ganglion Stimulator For Pain Relief	AXIUM NEUROSTIMULATOR SYSTEM (P150004)
Ophthalmics	Ophthalmic Prosthetic Devices	Other Ophthalmic Prosthetic Devices	29 Jul 16	9.3	Novartis	Intraocular Pressure Lowering Implant	CYPASS MICRO-STENT (P150037)
Ophthalmics	Ophthalmic Prosthetic Devices	Other Ophthalmic Prosthetic Devices	29 Jun 16	9.2	ReVision Optics	Implant, Corneal, Refractive	RAINDROP NEAR VISION INLAY (P150034)
Orthopedics	Joint Reconstruction	Extremity Implants	01 Jul 16	14.0	Cartiva	Prosthesis, Metatarsophalangeal Joint Cartilage Replacement Implant	CARTIVA SYNTHETIC CARTILAGE IMPLANT (P150017)
Orthopedics	Other Orthopedic Devices	Bone & Spinal Stimulators	08 Jan 16	85.4	Storz Medical	Generator, Shock-Wave, For Pain Relief	STORZ MEDICAL DUOLITH SD1 SHOCK WAVE THERAPY (P080028)
Wound Management	Wound Closure Devices	Surgical Sealants	11 Apr 16	11.5	C. R. Bard	Sealant, Polymerizing	TRIDYNE VASCULAR SEALANT (P150016)
<b>Average PMA FDA Review Time (mths)</b>				<b>14.9</b>			



## 2016 FDA 510(k) De Novo Clearances (to 31 August 2016)

Source: EvaluateMedTech® September 2016

EvaluateMedTech® Device Classification							
Level 1	Level 2	Level 3	Decision Date	FDA Review Time (mths)	Company	Product Code Name	Device Name (Approval Code)
Cardiology	Cardiovascular Surgical Devices	Vascular Closure Devices	27 Jul 16	13.2	Micro Interventional Devices	Apical Closure Device	PERMASEAL (DEN150029)
Endoscopy	Endoscopes	Laparoscopes	07 Apr 16	9.6	Advanced Surgical Concepts	Containment System, Laparoscopic Power Morcellation, With Instrument Port	PNEUMOLINER (DEN150028)
Gastroenterology	Gastrointestinal Therapeutic Devices	Biliary Devices	03 Jun 16	9.2	Boston Scientific	Biliary Stent System For Benign Strictures	WALLFLEX BILIARY RX FULLY COVERED STENT SYSTEM RMV (DEN150040)
General & Plastic Surgery	Surgical Instruments & Accessories	Other Surgical Instruments & Accessories	13 Jun 16	16.1	Levita Magnetics	Magnetic Surgical System	MAGNETIC SURGICAL SYSTEM (DEN150007)
In Vitro Diagnostics (IVD)	Immunoassays	Multiple Autoantibodies Immunoassays	25 Apr 16	9.8	Kronus	Aquaporin-4 Autoantibody	KRONUS AQUAPORIN-4 AUTOANTIBODY (AQP4AB) ELISA ASSAY (DEN150030)
In Vitro Diagnostics (IVD)	Immunoassays	Other Immunoassays	20 Feb 16	11.6	Thermo Fisher Scientific	Device To Detect And Measure Procalcitonin (Pct) In Human Clinical Specimens	B.R.A.H.M.S PCT SENSITIVE KRYPTOR (DEN150009)
In Vitro Diagnostics (IVD)	Molecular Diagnostics	Infectious Disease Molecular Diagnostics	28 Mar 16	3.4	Bio-Rad Laboratories	Assayed External Control Material For Microbiology Nucleic Acid Amplification (Nat) Assays	AMPLICHEK II, NEGATIVE AND AMPLICHEK II, NEGATIVE MINIPAK, AMPLICHEK II, LEVEL 1 AND AMPLICHEK II, LEVEL 1 MINIPAK, AMPLICHEK II, LEVEL 2 AND AMPLICHEK II, LEVEL 2 MINIPAK, AMPLICHEK II, LEVEL 3 AND AMPLICHEK II, LEVEL 3 MINIPAK (DEN150058)
In Vitro Diagnostics (IVD)	Molecular Diagnostics	Oncology Molecular Diagnostics	22 Jul 16	6.1	Asuragen	Bcr/Abl1 Monitoring Test	QUANTIDEX QPCR BCR-ABL IS KIT (DEN160003)
Neurology	Neurology Diagnostic Devices	Neurodiagnostic Systems	01 Aug 16	19.3	Jan Medical	Cranial Motion Measurement Device	NAUTILUS BRAINPULSE 1000 (DEN140040)
Neurology	Neurology Diagnostic Devices	Other Neurology Diagnostic Devices	22 Aug 16	12.4	ImPACT Applications	Computerized Cognitive Assessment Aid For Concussion	IMPACT COMPUTERIZED NEUROCOGNITIVE CONCUSSION MANAGEMENT AID (DEN150037)
Neurology	Neurology Therapeutic Devices	Other Neurology Therapeutic Devices	15 Jul 16	18.0	EPIC Research & Diagnostics	Evoked Photon Image Capture Device	EPIC CLEARVIEW SYSTEM (DEN150004)
Neurology	Neurology Therapeutic Devices	Other Neurology Therapeutic Devices	13 May 16	18.8	Cereve	Thermal System For Insomnia	CEREVE SLEEP SYSTEM (DEN140032)
Ophthalmics	Ophthalmic Diagnostic Devices	Other Ophthalmic Diagnostic Devices	08 Jun 16	29.9	REBIScan	Strabismus Detection Device	PEDIATRIC VISION SCANNER (DEN130051)
Ophthalmics	Ophthalmic Diagnostic Devices	Other Ophthalmic Diagnostic Devices	04 Mar 16	22.0	Sensimed	Ocular Pattern Recorder	SENSIMED TRIGGERFISH (DEN140017)
Ophthalmics	Ophthalmic Therapeutic Devices	Other Ophthalmic Therapeutic Devices	20 Apr 16	21.1	Innovatex	Tear Duct Occluder	GLAUCOMA COMPANION (DEN140022)
<b>Average 510(k) De Novo FDA Review Time (mths)</b>				<b>14.7</b>			

Note: Based on Devices@FDA data to 31 August 2016.

PMA (Pre-market Approval): a class III device which is a 'life-sustaining or life-supporting implantable device'; usually require trials.

HDE (Humanitarian Device Exemption): a device for treating or diagnosing a disease/condition that affects <4,000 individuals in the US per year.

510(k) De Novo Clearance: a device which poses a low risk and could ordinarily be cleared via the 510(k) route, but which is sufficiently innovative that no existing device may be used as a predicate.

# In Vitro Diagnostics (IVD) Market to 2022



## Roche Continues Domination of IVD field; 2022 Sales Forecast to Reach \$12.8bn.

EvaluateMedTech® consensus forecasts find that Roche's sales of diagnostic tests are expected to reach \$12.8bn in 2022, giving the company a market share of 18.1%.

Siemens is the fastest growing IVD company in the top ten with an

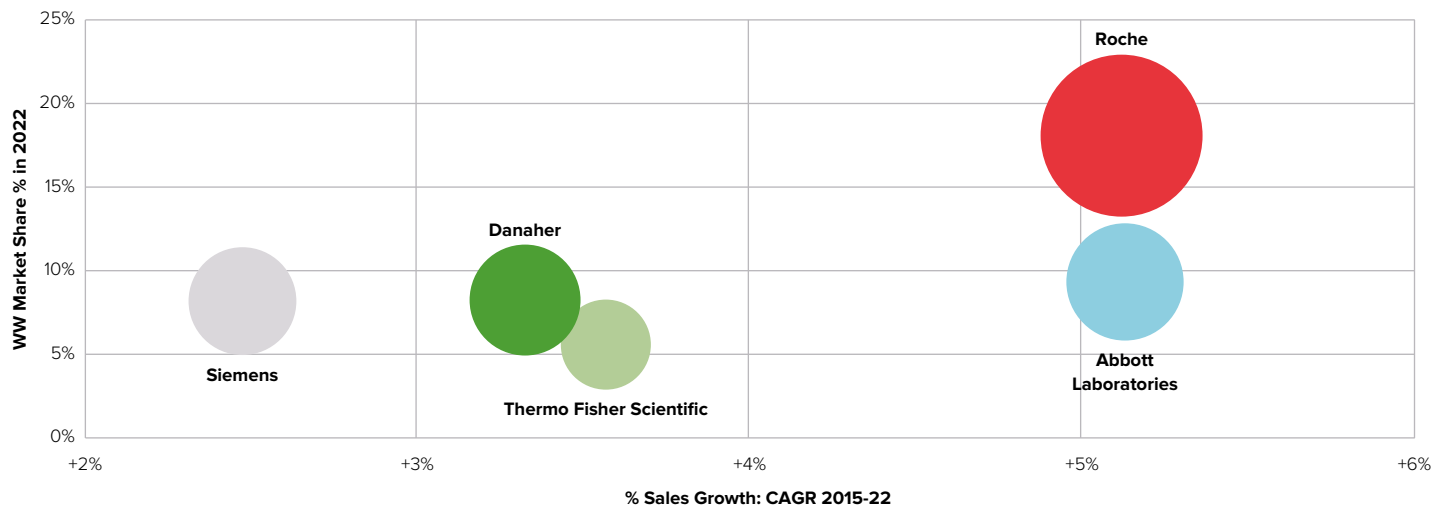
annual growth rate of 10.2% between 2015 and 2022. This will push the company up two places to sixth in the 2022 rankings.

The in vitro diagnostics market is estimated to grow at 5.6% (CAGR) between 2015 and 2022 to a worldwide total of \$70.8bn.

Should Abbott complete the acquisition of Alere it will close in on Roche, with potential sales of \$9.4bn in 2022.

## WW In Vitro Diagnostics Sales, Market Share & Sales Growth (2015-22)

Source: EvaluateMedTech® September 2016



Note: Bubble = WW Sales in 2022

## WW In Vitro Diagnostics Sales: Top 10 Companies & Total Market (2015/22)

Source: EvaluateMedTech® September 2016

Rank	Company	WW Sales (\$m)		CAGR 2015-22	WW Market Share		Rank Change 2015-22
		2015	2022		2015	2022	
1.	<b>Roche</b>	9,026	<b>12,800</b>	+5.1%	18.6%	18.1%	-
2.	<b>Abbott Laboratories</b>	4,646	<b>6,590</b>	+5.1%	9.6%	9.3%	+1
3.	<b>Danaher</b>	4,633	<b>5,823</b>	+3.3%	9.6%	8.2%	+1
4.	<b>Siemens</b>	4,855	<b>5,762</b>	+2.5%	10.0%	8.1%	-2
5.	<b>Thermo Fisher Scientific</b>	3,017	<b>3,854</b>	+3.6%	6.2%	5.4%	-
6.	<b>Systemx</b>	1,940	<b>3,835</b>	+10.2%	4.0%	5.4%	+2
7.	<b>Becton Dickinson</b>	2,690	<b>3,392</b>	+3.4%	5.6%	4.8%	-1
8.	<b>Alere</b>	2,238	<b>2,822</b>	+3.4%	4.6%	4.0%	-1
9.	<b>bioMérieux</b>	1,722	<b>2,716</b>	+6.7%	3.6%	3.8%	-
10.	<b>Ortho-Clinical Diagnostics</b>	1,700	<b>1,997</b>	+2.3%	3.5%	2.8%	-
<b>Top 10</b>		36,466	<b>49,590</b>	+4.5%	75.3%	70.0%	
<b>Other</b>		11,958	<b>21,235</b>	+8.5%	24.7%	30.0%	
<b>Total Industry</b>		<b>48,424</b>	<b>70,825</b>	+5.6%	100.0%	100.0%	

Note: Excludes Glucose Test Systems which are included in Diabetic Care classification.



# Cardiology Market to 2022



## Medtronic Continues to Dominate the Cardiology Market; Sales Forecast to Reach \$14.1bn in 2022.

EvaluateMedTech® consensus forecasts find that Medtronic retained its position as the top cardiology company in 2015 and is forecast to remain the world's leading heart device maker in 2022, with an expected market share of 22.6%. Edwards Lifesciences is forecast to be the fastest growing company between 2015 and 2022, with its

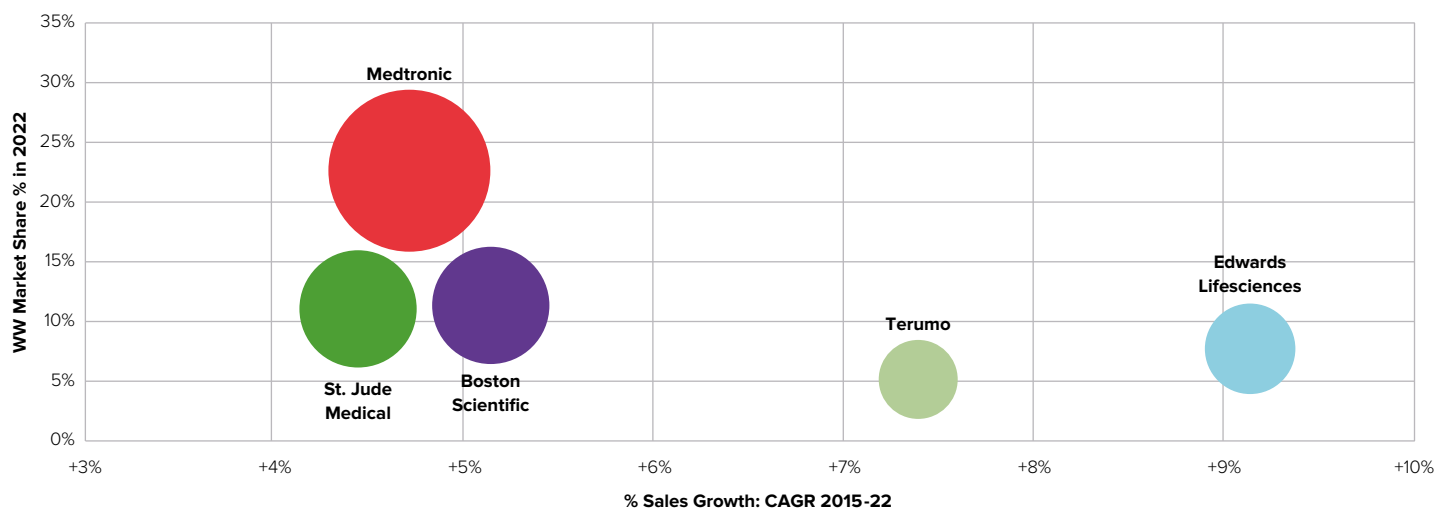
growth primarily driven by its transcatheter heart valve business and its plan to look beyond current technologies to the tricuspid valve.

Following Abbott's acquisition of St. Jude, it will become the second largest cardiology company, with 2022 sales forecast to reach \$9.9bn.

The cardiology industry is expected to grow at 5.7% (CAGR), with sales reaching \$62.3bn in 2022.

## WW Cardiology Sales, Market Share & Sales Growth (2015-22)

Source: EvaluateMedTech® September 2016



Note: Bubble = WW Sales in 2022

## WW Cardiology Sales: Top 10 Companies & Total Market (2015/22)

Source: EvaluateMedTech® September 2016

Rank	Company	WW Sales (\$m)			WW Market Share		Rank Change 2015-22
		2015	2022	CAGR 2015-22	2015	2022	
1.	<b>Medtronic</b>	10,218	<b>14,107</b>	+4.7%	24.3%	22.6%	-
2.	<b>Boston Scientific</b>	4,977	<b>7,068</b>	+5.1%	11.8%	11.3%	+1
3.	<b>St. Jude Medical</b>	5,066	<b>6,869</b>	+4.4%	12.0%	11.0%	-1
4.	<b>Edwards Lifesciences</b>	2,494	<b>4,599</b>	+9.1%	5.9%	7.4%	+1
5.	<b>Terumo</b>	1,936	<b>3,189</b>	+7.4%	4.6%	5.1%	+2
6.	<b>Abbott Laboratories</b>	2,688	<b>3,065</b>	+1.9%	6.4%	4.9%	-2
7.	<b>Johnson &amp; Johnson</b>	2,036	<b>2,500</b>	+3.0%	4.8%	4.0%	-1
8.	<b>W. L. Gore &amp; Associates</b>	1,725	<b>2,121</b>	+3.0%	4.1%	3.4%	-
9.	<b>Asahi Kasei</b>	1,171	<b>1,984</b>	+7.8%	2.8%	3.2%	+2
10.	<b>Getinge</b>	1,373	<b>1,724</b>	+3.3%	3.3%	2.8%	-1
	<b>Top 10</b>	33,683	<b>47,228</b>	+4.9%	80.0%	75.8%	
	<b>Other</b>	8,442	<b>15,069</b>	+8.6%	20.0%	24.2%	
	<b>Total Industry</b>	<b>42,125</b>	<b>62,297</b>	+5.7%	100.0%	100.0%	

Note: General Electric & Philips do not disclose cardiology sales.

# Diagnostic Imaging Market to 2022



## Siemens and General Electric to Retain Leading Positions in 2022.

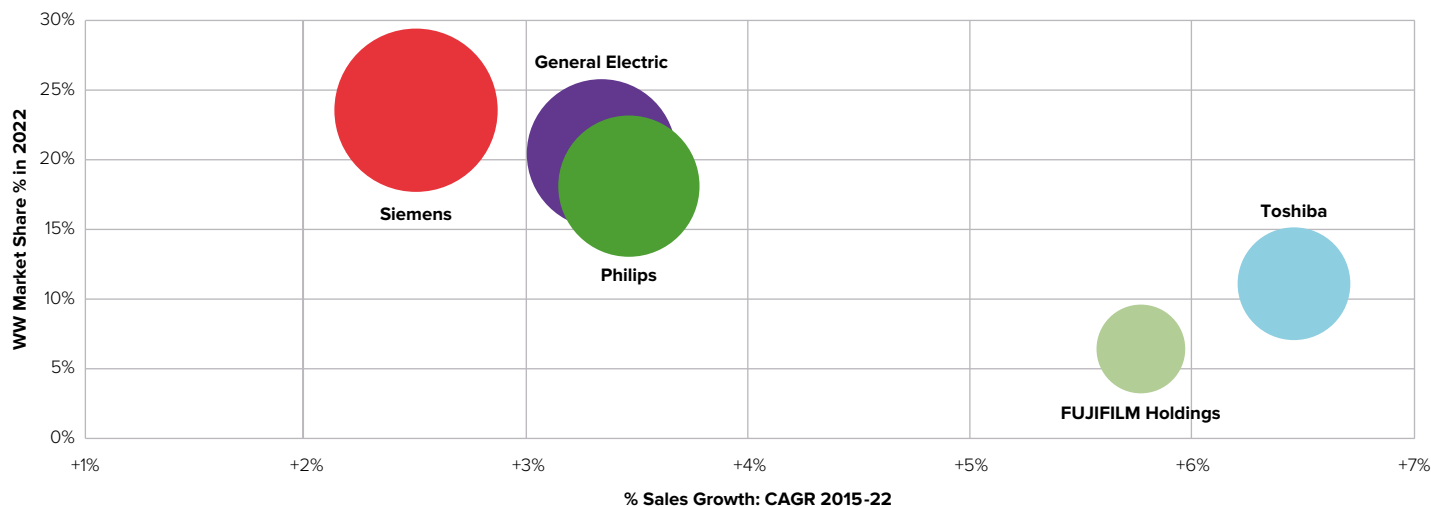
EvaluateMedTech® consensus forecasts find that diagnostic imaging is forecast to be the slowest growing device area, with its CAGR between 2015 and 2022 expected to be only 3.7%. Siemens is

expected to remain the world's leading diagnostic imaging company in 2022 with 23.6% of the market. General Electric will follow closely with a 20.3% share.

The diagnostic imaging market is set to grow from a global total of \$38.9bn in 2015 to \$50.3bn in 2022.

## WW Diagnostic Imaging Sales, Market Share & Sales Growth (2015-22)

Source: EvaluateMedTech® September 2016



Note: Bubble = WW Sales in 2022

## WW Diagnostic Imaging Sales: Top 10 Companies & Total Market (2015/22)

Source: EvaluateMedTech® September 2016

Rank	Company	WW Sales (\$m)		CAGR 2015-22	WW Market Share		Rank Change 2015-22
		2015	2022		2015	2022	
1.	Siemens	9,995	11,880	+2.5%	25.7%	23.6%	-
2.	General Electric	8,115	10,210	+3.3%	20.9%	20.3%	-
3.	Philips	7,198	9,129	+3.5%	18.5%	18.2%	-
4.	Toshiba	3,641	5,647	+6.5%	9.4%	11.2%	-
5.	FUJIFILM Holdings	2,198	3,256	+5.8%	5.7%	6.5%	-
6.	Carestream Health	1,357	1,786	+4.0%	3.5%	3.6%	-
7.	Hitachi	1,032	1,383	+4.3%	2.7%	2.8%	-
8.	Konica Minolta	749	1,142	+6.2%	1.9%	2.3%	-
9.	Shimadzu	539	800	+5.8%	1.4%	1.6%	+3
10.	Varian Medical Systems	611	740	+2.8%	1.6%	1.5%	-
	<b>Top 10</b>	35,433	45,973	+3.8%	91.1%	91.4%	
	<b>Other</b>	3,445	4,314	+3.3%	8.9%	8.6%	
	<b>Total Industry</b>	<b>38,878</b>	<b>50,287</b>	<b>+3.7%</b>	<b>100.0%</b>	<b>100.0%</b>	

Note: Segment sales include servicing of equipment.

# Orthopedics Market to 2022



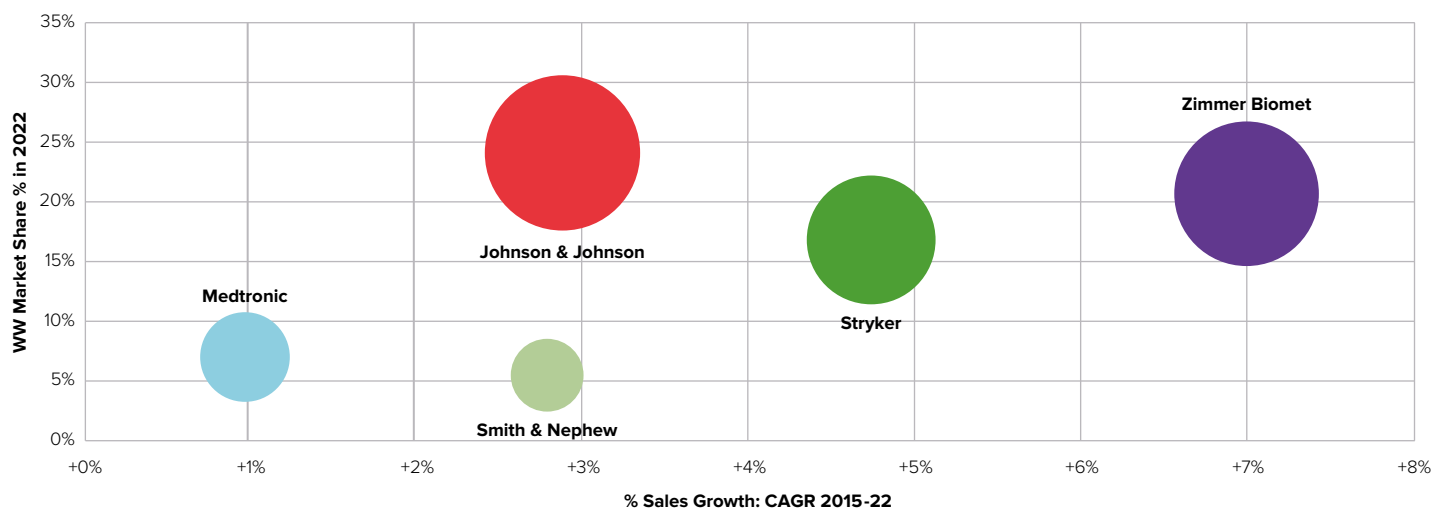
## J&J and Zimmer Biomet Leading Companies in Orthopedics in 2022 with Zimmer Biomet Set to Experience Strong Growth.

EvaluateMedTech® consensus forecasts find that Johnson & Johnson will remain the world's number one orthopedic company in 2022, despite substantial growth for Zimmer Biomet, which is expected to expand by 7.0% (CAGR) and hold 20.6% of the market in 2022.

Wright Medical Group is forecast to grow by 16.9% (CAGR) between 2015 and 2022, thanks to its streamlining into a pure extremities and biologics company with the company's merger with Tornier last year.

## WW Orthopedics Sales, Market Share & Sales Growth (2015-22)

Source: EvaluateMedTech® September 2016



Note: Bubble = WW Sales in 2022

## WW Orthopedics Sales: Top 10 Companies & Total Market (2015/22)

Source: EvaluateMedTech® September 2016

Rank	Company	WW Sales (\$m)		CAGR 2015-22	WW Market Share		Rank Change 2015-22
		2015	2022		2015	2022	
1.	Johnson & Johnson	8,721	10,631	+2.9%	25.6%	24.1%	-
2.	Zimmer Biomet	5,662	9,104	+7.0%	16.6%	20.6%	-
3.	Stryker	5,373	7,426	+4.7%	15.8%	16.8%	-
4.	Medtronic	2,923	3,127	+1.0%	8.6%	7.1%	-
5.	Smith & Nephew	1,984	2,404	+2.8%	5.8%	5.5%	-
6.	Arthrex	1,592	2,090	+4.0%	4.7%	4.7%	-
7.	NuVasive	811	1,296	+6.9%	2.4%	2.9%	+1
8.	Wright Medical Group	415	1,238	+16.9%	1.2%	2.8%	+3
9.	Globus Medical	545	1,001	+9.1%	1.6%	2.3%	-
10.	Orthofix International	396	516	+3.8%	1.2%	1.2%	+2
	<b>Top 10</b>	<b>28,424</b>	<b>38,833</b>	<b>+4.6%</b>	<b>83.5%</b>	<b>88.0%</b>	
	<b>Other</b>	<b>5,600</b>	<b>5,279</b>	<b>-0.8%</b>	<b>16.5%</b>	<b>12.0%</b>	
	<b>Total Industry</b>	<b>34,024</b>	<b>44,113</b>	<b>+3.8%</b>	<b>100.0%</b>	<b>100.0%</b>	

# Ophthalmics Market to 2022



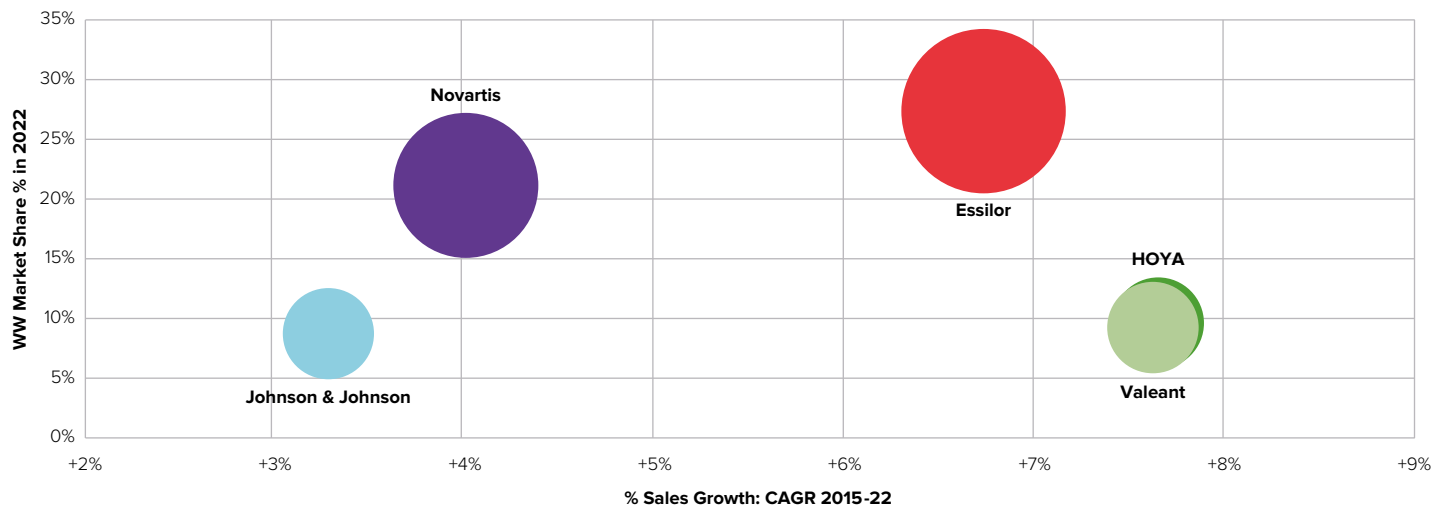
## Essilor Leads Ophthalmics Market in 2022.

EvaluateMedTech® consensus forecasts find that lens maker Essilor International will be the leading company in ophthalmic technology in 2022, with sales of \$10.2bn. Novartis takes second place with sales of \$7.9bn.

J&J's upcoming acquisition of Abbott Medical Optics will allow the company to retain its third place position in 2022, with ophthalmic sales forecast to reach \$4.8bn.

## WW Ophthalmics Sales, Market Share & Sales Growth (2015-22)

Source: EvaluateMedTech® September 2016



Note: Bubble = WW Sales in 2022

## WW Ophthalmics Sales: Top 10 Companies & Total Market (2015/22)

Source: EvaluateMedTech® September 2016

Rank	Company	WW Sales (\$m)			WW Market Share		Rank Change 2015-22
		2015	2022	CAGR 2015-22	2015	2022	
1.	Essilor International	6,479	10,211	+6.7%	26.0%	27.5%	-
2.	Novartis	5,999	7,902	+4.0%	24.1%	21.3%	-
3.	HOYA	2,128	3,564	+7.6%	8.5%	9.6%	+1
4.	Valeant Pharmaceuticals International	2,046	3,418	+7.6%	8.2%	9.2%	+1
5.	Johnson & Johnson	2,608	3,272	+3.3%	10.5%	8.8%	-2
6.	Carl Zeiss	2,015	2,656	+4.0%	8.1%	7.2%	-
7.	The Cooper Companies	1,488	2,149	+5.4%	6.0%	5.8%	-
8.	Abbott Laboratories	1,133	1,550	+4.6%	4.5%	4.2%	-
9.	TOPCON	365	678	+9.2%	1.5%	1.8%	-
10.	NIDEK	296	508	+8.0%	1.2%	1.4%	-
	<b>Top 10</b>	<b>24,557</b>	<b>35,907</b>	<b>+5.6%</b>	<b>98.5%</b>	<b>96.8%</b>	
	<b>Other</b>	<b>369</b>	<b>1,184</b>	<b>+18.1%</b>	<b>1.5%</b>	<b>3.2%</b>	
	<b>Total Industry</b>	<b>24,926</b>	<b>37,091</b>	<b>+5.8%</b>	<b>100.0%</b>	<b>100.0%</b>	



## M&A Activity in H1 2016 Slumps 79% to \$17bn following 2015's Flurry of Mega Mergers.

EvaluateMedTech® found that the total value of all M&As in H1 2016 decreased by 79% to \$17bn compared with the extraordinary activity in H1 2015 that came to \$84bn in total. Conversely, the number of deals increased 18% from H1 2015 to H1 2016.

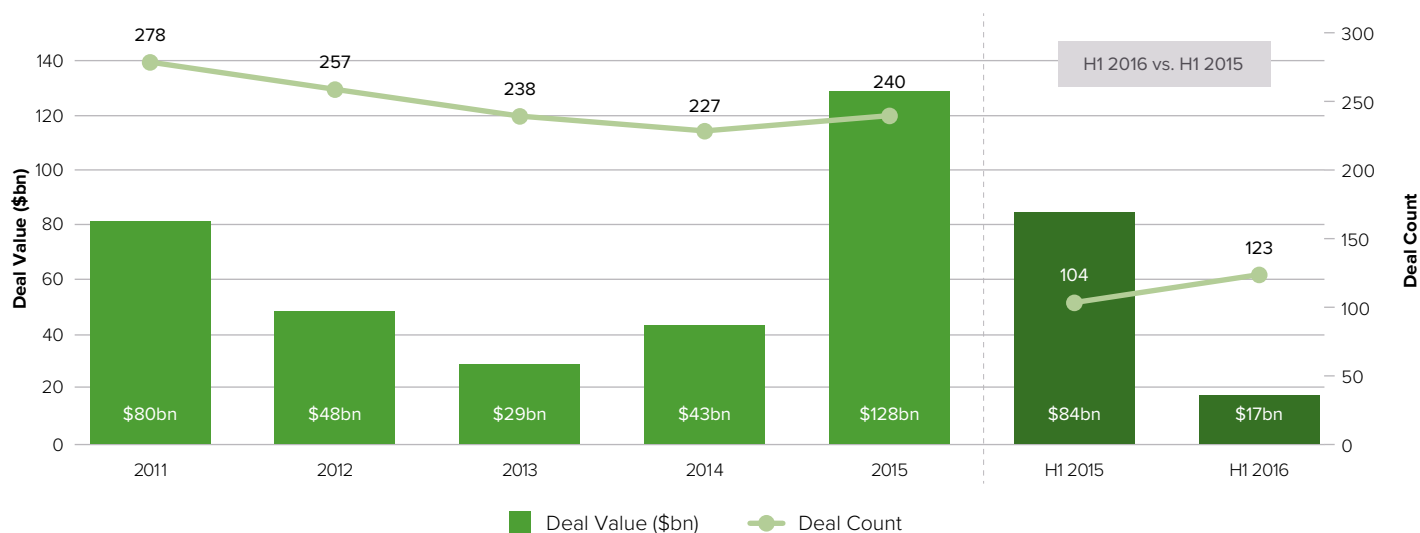
The biggest deal in H1 2016 was the dental market consolidation of

DENTSPLY and Sirona – effectively producing the world's largest maker of dental products.

Abbott Laboratories' potential acquisitions of St. Jude Medical and Alere, valued at \$25bn and \$6bn respectively, are scheduled to close in Q4 2016, though the acquisition of Alere remains in doubt owing to investigations into the accounting practices of the company.

## Count of Medtech M&A Deals vs. Total Medtech M&A Value (2011 - H1 2016)

Source: EvaluateMedTech® September 2016



## Key M&A Deals

H1 2016: DENTSPLY – Sirona Dental Systems (\$5.5bn); Stryker – Sage Products (\$2.8bn); Thermo Fisher Scientific – Affymetrix (\$1.3bn); Stryker – Physio-Control (\$1.3bn)

2015: Medtronic – Covidien (\$49.9bn); Zimmer – Biomet (\$14.0bn); Becton Dickinson – CareFusion (\$12.2bn)

2014: Thermo-Fisher – Life Technologies (\$13.6bn); Carlyle Group (PE) – J&J's Ortho-Clinical Diagnostics unit (\$4.2bn)

2013: Valeant Pharmaceuticals – Bausch + Lomb (\$8.7bn); Baxter – Gambro (\$3.9bn)

2012: Johnson & Johnson – Synthes (\$19.7bn); Hologic – Gen-Probe (\$3.7bn)

2011: Novartis – Alcon\* (\$9.6bn); Sanofi – Genzyme\* (\$20.1bn); Danaher – Beckman Coulter (\$6.8bn); Apax Group (PE) – Kinetic Concepts (\$6.1bn); Thermo-Fisher – Phadia (\$3.4bn)

## Count of Medtech Closed M&A Deals vs. Total Medtech M&A Value (2011 - H1 2016)

Source: EvaluateMedTech® September 2016

Period	2011	2012	2013	2014	2015	H1 2015	H1 2016
Deal Count	278	257	238	227	240	104	123
% Chg.		-8%	-7%	-5%	6%		18%
Deal Value (\$bn)	80	48	29	43	128	84	17
% Chg.		-40%	-40%	50%	196%		-79%



## Top 10 Medtech M&A Deals Closed: Ranked on Deal Value (H1 2016)

Source: EvaluateMedTech\* September 2016

Rank	Target	Country (Status)	Acquiror	Completion Date	Deal Value (\$m)
1.	<b>Sirona Dental Systems</b>	Germany (Listed)	DENTSPLY Sirona	29 Feb 16	5,507
2.	<b>Sage Products</b>	USA (Private)	Stryker	01 Apr 16	2,775
3.	<b>Affymetrix</b>	USA (Listed)	Thermo Fisher Scientific	31 Mar 16	1,300
4.	<b>Physio-Control</b>	USA (Private)	Stryker	05 Apr 16	1,280
5.	<b>Diabetes Care business of Bayer</b>	Germany (Business Unit)	Panasonic	05 Jan 16	1,110
6.	<b>Creganna Medical</b>	Ireland (Private)	TE Connectivity	04 Apr 16	895
7.	<b>Brightree</b>	USA (Private)	ResMed	04 Apr 16	800
8.	<b>Ellipse Technologies</b>	USA (Private)	NuVasive	11 Feb 16	410
9.	<b>Focus Diagnostics</b>	USA (Business Unit)	DiaSorin	13 May 16	300
10.	<b>Aesynt</b>	USA (Private)	Omniceil	05 Jan 16	275
	<b>Other</b>				2,822
	<b>Total</b>				<b>17,473</b>

Note: Analysis based on closing date of deal.

\*Alcon & Genzyme included in analysis as >25% of company sales are derived from medtech.



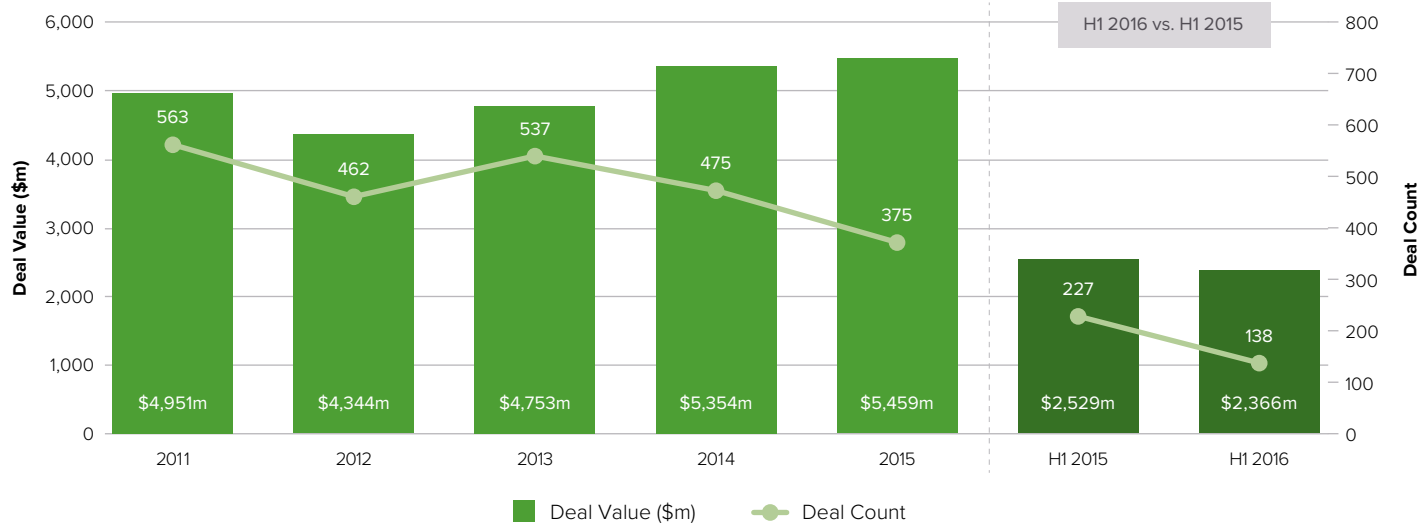
## Number of Venture Financing Deals Slumps 39% to 138 in H1 2016; Value of Venture Financing Only Falls 6% to \$2.4bn.

Venture capital continues its trend towards fewer deals in 2016 with only 138 funding rounds in the first half of the year, compared with 227 in the first half of 2015. The total value of these deals, however, is

remarkably similar, with only a 6% decline in the total deal value. The standout round in the first half of the year is the USA-based, oncology-focused healthcare IT company Flatiron Health with its \$175m series C round in January.

### Count of Financing Deals vs. Total Financing Value (2011 - H1 2016)

Source: EvaluateMedTech® September 2016



### Count of Medtech Financing Deals vs. Total Financing Value (2011 - H1 2016)

Source: EvaluateMedTech® September 2016

Period	2011	2012	2013	2014	2015	H1 2015	H1 2016
Deal Count	563	462	537	475	375	227	138
% Chg.		-18%	16%	-12%	-21%		-39%
Deal Value (\$m)	4,951	4,344	4,753	5,354	5,459	2,529	2,366
% Chg.		-12%	9%	13%	2%		-6%



**Top 10 Medtech Venture Financing Deals: Ranked on Deal Value (H1 2016)**

Source: EvaluateMedTech® September 2016

Rank	Company	Primary Focus	Country	Financing Round	Date	Deal Value (\$m)
1.	<b>Flatiron Health</b>	Healthcare IT	USA	Series C	06 Jan 16	175
2.	<b>Guardant Health</b>	In Vitro Diagnostics (IVD)	USA	Series D	07 Jan 16	100
3.	<b>Acutus Medical</b>	Cardiology	USA	Series C	22 Mar 16	75
4.	<b>Heartflow</b>	Cardiology	USA	Series E	20 May 16	64
5.	<b>Exosome Diagnostics</b>	In Vitro Diagnostics (IVD)	USA	Series B	07 Jan 16	60
6.	<b>TransMedics</b>	General & Plastic Surgery	USA	Series Undisclosed	26 May 16	51
7.	<b>Proteus Digital Health</b>	Patient Monitoring	USA	Series H	15 Apr 16	50
8.	<b>Alcresta Therapeutics</b>	Gastroenterology	USA	Series C	14 Jun 16	49
9.	<b>CVRx</b>	Cardiology	USA	Series Undisclosed	14 Jun 16	47
10.	<b>Quanterix</b>	In Vitro Diagnostics (IVD)	USA	Series D	23 Mar 16	46
	<b>Other</b>					1,649
	<b>Total</b>					<b>2,366</b>

Note: Includes investments in medtech companies only. Does not include pharmaceutical, biotech or genomic companies. Includes Private Investment in Public Equity (PIPE).





## MedTech IPO Deal Values Fall Significantly in H1 2016 to \$164m.

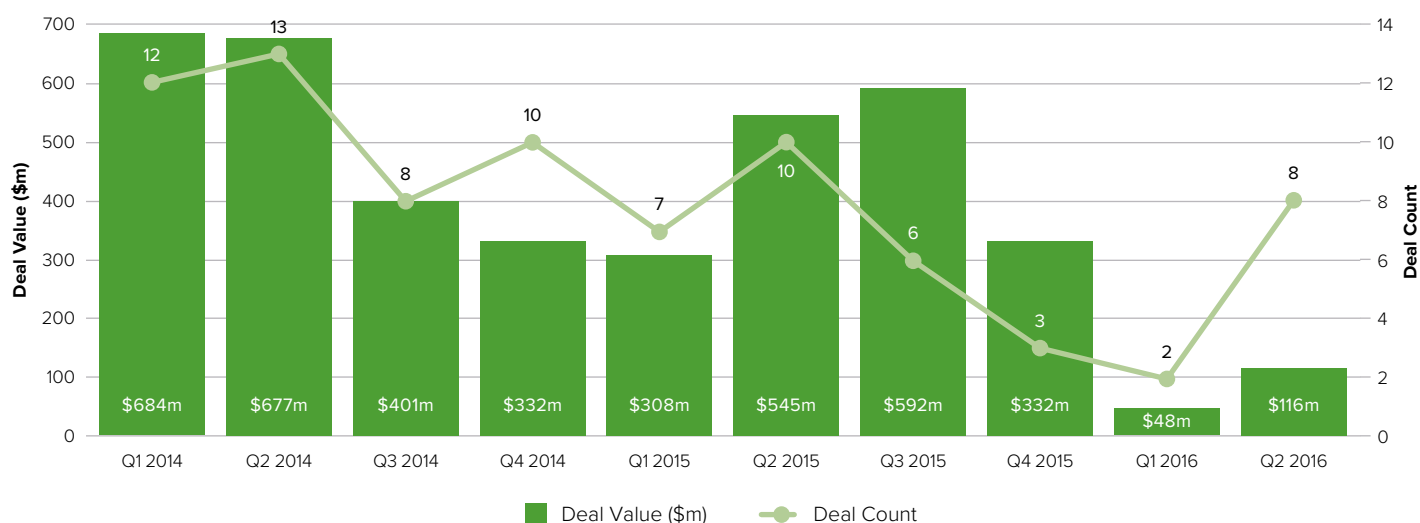
The first half of 2016 has seen a dramatic drop in the amount of funding raised through initial public offerings. In the first half of 2015, \$853m was raised, compared with a meagre \$164m in the first half of 2016.

The number of IPOs has also continued to decline, with only ten IPOs in the first half of 2016, as opposed to 25 in H1 2014 and 17 in H1 2015.

The biggest IPO in H1 2016 is the \$45m NYSE listing of Senseonics, developer of the Eversense™ Continuous Glucose Monitoring System.

## Quarterly Count of IPO Deals vs. Total IPO Value (Q1 2014 - Q2 2016)

Source: EvaluateMedTech® September 2016



## Count of Medtech IPO Deals vs. Total IPO Value (Q1 2014 - Q2 2016)

Source: EvaluateMedTech® September 2016

Quarter	Q1 2014	Q2 2014	Q3 2014	Q4 2014	Q1 2015	Q2 2015	Q3 2015	Q4 2015	Q1 2016	Q2 2016
Deal Count	12	13	8	10	7	10	6	3	2	8
% Chg. from previous quarter		8%	-38%	25%	-30%	43%	-40%	-50%	-33%	300%
Deal Value (\$m)	684	677	401	332	308	545	592	332	48	116
% Chg. from previous quarter		-1%	-41%	-17%	-7%	77%	9%	-44%	-85%	141%



## Top 10 Medtech IPO Deals: Ranked on Deal Value (H1 2016)

Source: EvaluateMedTech® September 2016

Rank	Company	Primary Focus	Country	Stock Exchange	Date	Deal Value (\$m)
1.	<b>Senseonics</b>	Diabetic Care	USA	NYSE	18 Mar 16	45
2.	<b>ASIT biotech</b>	In Vitro Diagnostics (IVD)	Belgium	Euronext	10 May 16	27
3.	<b>Valeritas</b>	Drug Delivery	USA	OTC Markets	03 May 16	25
4.	<b>Pulse Biosciences</b>	Radiology	USA	Nasdaq	18 May 16	20
5.	<b>Oncimmune</b>	In Vitro Diagnostics (IVD)	United Kingdom	London Stock Exchange (LSE)	18 May 16	16
6.	<b>Sensus Healthcare</b>	Oncology	USA	Nasdaq	03 Jun 16	11
7.	<b>Volpara Solutions</b>	Diagnostic Imaging	New Zealand	Australian Securities Exchange (ASX)	27 Apr 16	10
8.	<b>PAVMED</b>	Various	USA	Nasdaq	28 Apr 16	5
9.	<b>SunBio</b>	Various	South Korea	KOSDAQ	22 Jan 16	3
10.	<b>Osteonic</b>	Orthopedics	South Korea	KOSDAQ	04 May 16	2
<b>Total</b>						<b>164</b>

Note: Does not include pharmaceutical or biotech companies.

Excludes the following IPOs: NantHealth Q2 2016, Fitbit Q2 2015; Circassia Q1 2014, for which medtech is not a primary focus.



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