



Vital Signs: **MedTech**

Devices, diagnostics, and surgical innovation

22 SEP
19 OCT



What decides whether your device waits two years for its second market

What decides how long a device waits for its second market, and what this month's purchases and funding rounds show a company about itself.

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In recent examples, approval in a second market came up to about two years after the first (our calculation)^{1,8}

2 years \$400m \$2.1bn \$250m

about, Aletta's wait from CE mark to FDA authorisation, the longest here (our calculation)^{1,16}

about what Stryker is investing in CMR Surgical, with an exclusive option to buy all of CMR¹⁹

STERIS's cash at closing for Xodus Medical, the top of this month's range of agreed prices^{50,70}

Precision Neuroscience's Series D, the largest round in this month's list⁸⁴

Every figure is the edition's own, with its numbered source; the pieces give the detail.

WHAT IT MEANS FOR YOU

Founders and start-ups

Applies to you if you are choosing between a CE mark and an FDA submission as your first filing.

01 Second markets · page 3

Established companies

Applies to you if you run a company with several product lines, or you want a larger company to buy yours.

02 Buyers · page 6

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Applies to you if you are pricing the sale of a device or diagnostics company.

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Following the sector

Applies to you if you or a relative might need heart valve or lymphatic surgery, or you are building or funding a surgical robot or instrument.

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SECTION 01

Second markets

How long a device waits for its second market

MARKET ENTRY Founders

What decides whether your device waits two years for its second market

In recent examples, approval in the second market came up to about two years after the first (our calculation), with devices going Europe first and US first, and MedTech Dive, a news site, reported that one robot maker's halted US launch delayed its entry by a year^{1,2,3,4,5,6}.

Novocure's Optune Pax, a pancreatic cancer device, announced FDA approval first and a CE mark about 4.6 months later (our calculation)⁴. FDA approval, from the US regulator, lets a maker sell a device for a stated use. FDA clearance and authorisation do the same. A CE mark is the EU's marking that lets a device be sold there.

Diabeloop's DBLG2 system went the other way and reached FDA clearance about 4.5 months after its CE mark (our calculation)⁷.

Device and maker	First market	Second market	Gap (our calculation)
Affera Prism-2 mapping software, Medtronic ⁸	FDA and CE mark announced together, 30 September 2026	Same release	None between announcements
DBLG2 system, Diabeloop ^{7,9}	CE mark, 4 August 2025	FDA clearance, 19 December 2025	About 4.5 months

Device and maker	First market	Second market	Gap (our calculation)
Optune Pax, Novocure ^{4,5,10}	FDA approval announced 11 February 2026	CE mark announced 30 June 2026; Japan approved 30 September 2026	About 4.6 months to Europe; about 7.6 months to Japan
da Vinci 5 cardiac use, Intuitive (robotic-assisted surgery) ^{11,12}	US leg: FDA clearance, January 2026 (Japan had cleared it in June 2025)	EU certification, September 2026	About 8 months, US to EU
SAPIEN M3 mitral valve, Edwards ^{13,14}	CE mark announced 14 April 2025	FDA approval announced 23 December 2025	About 8.3 months
PerQseal Elite closure device, Haemonetics ^{2,3,15}	CE mark announced 22 April 2025	FDA approval announced 19 October 2026	About 18 months
Aletta blood-draw robot, Vitestro ^{1,16}	CE mark, August 2024	FDA authorisation announced 20 August 2026	About 2 years

An announcement can trail a decision. Insera Therapeutics announced its FDA clearance on 28 September 2026, about three months after the FDA decided on 24 June (our calculation)^{17,18}. A gap measured from announcements can be wrong, so take milestone dates from the regulator's own database.

A company's own choice can delay a sale. CMR Surgical, a UK maker of the Versius surgical robot, halted its planned US launch to wait for Versius Plus, the newer version^{6,19,20}. MedTech Dive, a news site that interviewed CMR's chief executive, reported that the halt delayed CMR's US market entry by a year⁶.

CMR's route into US hospitals runs through Stryker, which becomes its exclusive US sales agent for Versius once a deal announced on 12 October 2026 closes^{19,21}.

A rival reading is that the US route sets the gap. Aletta, the longest wait, came through the FDA's De Novo route, which is for a new kind of device with no equivalent on the market^{1,22}.

NAMSA, a device consultancy, advised on 21 October 2026 that high-cost devices needing the US market often do better filing there first²³.

Write the second market's evidence plan before the first filing.

HEALTHSEED PERSPECTIVE

Start local, think global. Choose the first market for where your first paying customer and your evidence already sit, and run the second market as its own project from the first day.

The strongest case against this is the industry's own choice. In a 2022 collaboration between UCLA Biodesign and BCG (Boston Consulting Group), 89% of companies said they would prioritise US approval in a survey of more than 100 senior medtech executives²⁴.

MedTech Europe, a trade association, reports in its 2024 survey a fall of 33% for large and 19% for small device companies in choosing the EU as their first market²⁵. The fall is measured from 26 May 2021, when the Medical Device Regulation (the EU's law for medical devices) began to apply, to that survey^{25,26}.

If your customer and your evidence sit in the US, this position says go there first. Our examples are few, so treat start local, think global as a rule of thumb. Diabeloop filed in the US before it held its CE certificate and reached FDA clearance about 4.5 months after its CE mark (our calculation): that is the second market run as its own project before the first was certified^{7,9}.

Daren Wilson, Co-Founder, Senior Partner

APPLIES TO YOU IF Founders

you are choosing between a CE mark and an FDA submission as your first filing.

SECTION 02

Buyers

CLASS OF COMPANIES OR TREND Established

Analysts tied some of this month's purchases to the buyer's own sales reach, a test a board can apply to its own product lines

A board can test its product lines by asking whether a larger buyer's sales reach would sell more of a line than its present owner can, which is our reading of how analysts explained some purchases^{27,28,29}. STERIS, a provider of products that support patient care, agreed to buy Xodus Medical, a specialty surgical products business^{30,31}. An analyst at Stephens, a financial services firm, says STERIS may lift Xodus sales through its larger sales network^{27,32}.

The seven companies in the table report annual revenue above the equivalent of \$1 billion^{33,34,35,36,37,38,39}.

Company	What it did	Reason given
Medtronic ^{40,41,42}	Completed the split-off of MiniMed Group, which listed its shares in March 2026, on 15 October: shareholders swapped Medtronic shares for MiniMed shares, so Medtronic no longer holds a stake and no cash was paid	Clear strategic focus on three portfolios: Cardiovascular, Neuroscience, and Surgical
Siemens Healthineers ⁴³	Stopped selling its general-imaging ultrasound systems from 12 October	General-imaging ultrasound is a well-served market
Johnson & Johnson ⁴⁴	Leaning towards spinning off DePuy Synthes, its orthopaedics business, said 13 October	The business's performance and momentum
STERIS ^{31,45}	Agreed to buy Xodus Medical, 11 October	Adds consumables used in the operating room (supplies that run out and are reordered)
GE HealthCare ⁴⁶	Agreed to buy SOFIE Biosciences, 5 October	A footprint in the final, time-critical stage of US supply of PET tracers, the imaging agents used in PET scans

Company	What it did	Reason given
Labcorp ^{29,47,48}	Agreed to buy BioReference assets from OPKO, announced 15 October	Analysts: 4Kscore, an FDA-approved blood test that helps predict aggressive prostate cancer, is a differentiated asset that Labcorp can take to wider use
Agilent Technologies, a supplier of analytical and clinical laboratory technologies ^{28,49,50}	Agreed to buy Proscia, a pathology software provider, 13 October	Analysts: a way into pathology software and cross-selling to existing customers

In our reading, these reasons give a board two tests: is the market already well served, and does the line fit the focus the company would state publicly? Johnson & Johnson's reason, performance, fits neither, and Medtronic gave no reason beyond focus^{40,44}.

Solventum, which plans to separate its health information systems business, sold its purification and filtration business for about \$4.1 billion to pay down debt and fund a wound-care purchase^{51,52}. Its strategy chief, in remarks MedTech Dive reported on 21 October 2026, said leaders should ask whether they are the right owner of a unit that is not getting the resources it needs⁵¹.

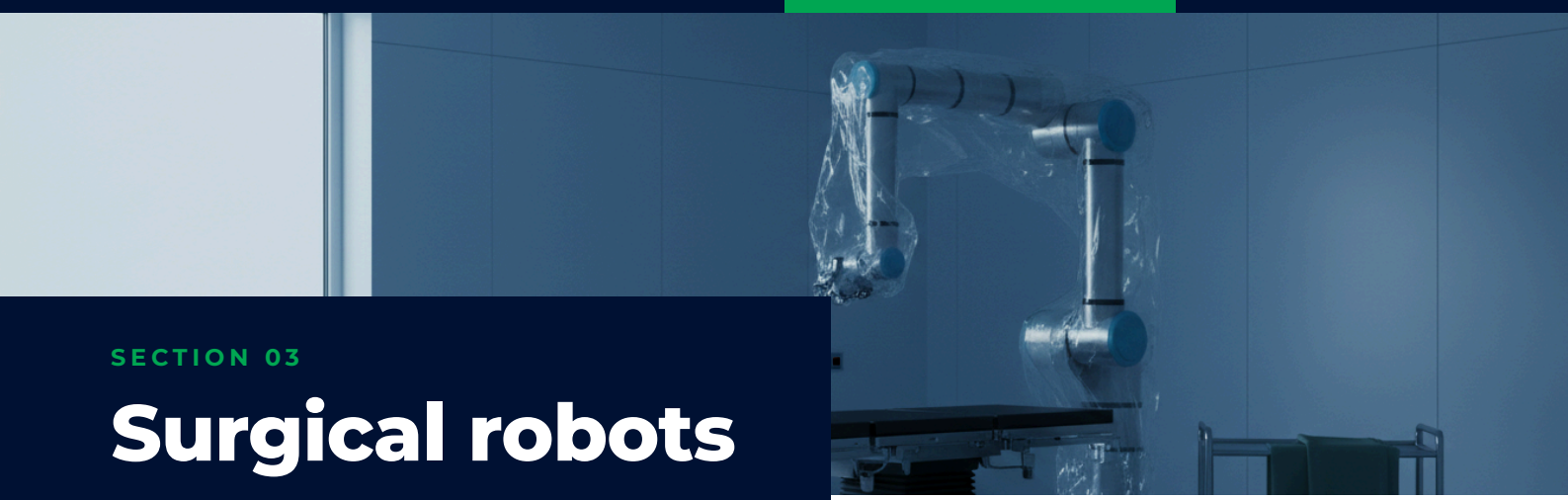
The Stephens analyst describes sales added to the buyer's sales network²⁷, and the medtech mergers and acquisitions adviser A.E. Cooper Medtech Ventures describes capability added to platforms the buyer already owns⁵³. In our reading, both are a buyer adding to what it already runs. A start-up can describe itself in a buyer's terms years before a sale.

The month does not fit one pattern. Johnson & Johnson's orthopaedics sales rose 3.2% in the third quarter of 2026⁵⁴, so the line it may spin off is still growing, and the adviser says a divestiture does not necessarily signal technological failure⁵³. GE HealthCare gave a supply reason for its purchase, so the sales-reach reading does not cover every deal⁴⁶.

In our reading, whole-company purchases also continue alongside capability buys. Integer Holdings, which develops and makes medical devices for other device companies, announced on 3 August 2026 that the private equity firm KKR had agreed to buy it^{55,56}.

APPLIES TO YOU IF Established

you run a company with several product lines, or you want a larger company to buy yours.



SECTION 03

Surgical robots

CLASS OF COMPANIES OR TREND Following the sector

Surgical robots are now used in microsurgery and permitted for heart surgery, so a patient may be offered one for operations long done by hand

A patient may now be offered a robot for lymphatic surgery, an operation for swelling after cancer treatment that surgeons have long done by hand^{57,58}. A review found robotic lymphatic surgery possible and safe in the short term, and it cannot yet say whether the results are better⁵⁷. Intuitive, a company in robotic-assisted surgery, is now permitted to sell its da Vinci 5 surgical robot for selected heart operations in three markets^{11,12,59,60}.

Symani, a microsurgery robot made by Medical Microinstruments (MMI), is used in lymphatic surgery^{57,58}. The review covered seven studies and 134 patients⁵⁷.

The robotic step took longer on average, 25.7 minutes against 11 minutes by hand, though in three studies robotic time fell with experience⁵⁷. Nicholas Panetta, chief of the Tampa General Hospital Plastic and Burn Surgery Institute, told Tampa Bay Business and Wealth in July 2026 that Symani leads to better outcomes⁶¹. The review does not support that claim⁵⁷.

In our reading, a robot wins each new operation through its own clearance. Versius, the robot of CMR Surgical, is cleared in the US for gallbladder removal only⁶². Stryker is to become Versius's exclusive US sales agent once a deal announced on 12 October 2026 closes, so its US sales of Versius would stay within that one clearance^{19,21,62}.

Medtronic's Hugo robotic surgery system is cleared for urology, with general surgery and gynaecology filed in June 2026^{63,64,65}. One clearance can cover several operations, as the FDA's January 2026 clearance of da Vinci 5 covered nine heart procedures, including heart valve repair⁵⁹.

Proof that a robot does better comes later and costs new money: MMI says its funding round, announced on 8 October 2026, pays partly for clinical evidence⁵⁸. That includes REMIND, an early study of Symani in lymphatic surgery for people with Alzheimer's disease, which MMI says could expand the uses of Symani^{58,66}.

Heart surgery is a return for robots. Beyond the FDA clearance above, Japan cleared da Vinci 5 for select cardiac uses in June 2025¹¹. In September 2026 da Vinci 5 received EU certification for adult cardiac surgery, including minimally invasive coronary artery bypass, bypass surgery through small cuts^{11,60}.

Intuitive's first cardiac procedures were done in France and Germany in 1998, and it says technical limitations and no dedicated training infrastructure led it to focus on other operations⁶⁰.

Operation	Robot and maker	Status
Microsurgery	Symani, MMI	FDA-authorised and CE marked; the approved uses vary by geography ⁵⁸
Selected heart procedures	da Vinci 5, Intuitive	FDA clearance January 2026; EU certification September 2026 ^{59,60}
Gallbladder removal in adults	Versius, CMR Surgical	The only US clearance, in adults 22 and older ⁶²
General surgery	OTTAVA, Johnson & Johnson	FDA authorisation announced 22 July 2026 ⁶⁷
Urology	Hugo, Medtronic	FDA clearance announced 3 December 2025; general surgery and gynaecology filings submitted in June 2026 ^{64,65}
Lymphatic surgery in people with Alzheimer's disease and confirmed lymphatic abnormalities	Symani, MMI	Early study of up to 15 patients; this use is not cleared for sale in the US ⁶⁶

The trend may be thinner than it looks, since Intuitive's early cardiac use did not take hold⁶⁰ and outcome studies could find no gain over manual operations, which the review has not ruled out⁵⁷.

If you are offered a robotic operation, ask how many the team has done, because robotic time fell with experience in three studies⁵⁷, and ask what evidence exists for your operation.

APPLIES TO YOU IF Following the sector	you or a relative might need heart valve or lymphatic surgery, or you are building or funding a surgical robot or instrument.
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Briefs: five shorter pieces from this edition, each traced to its sources

DO AND DON'T Founders

A partner that sells your device and buys into your company can limit who may buy you later

A larger company that sells your product and takes a stake could gain a say over who can buy you later. Stryker is investing in the UK surgical robot maker CMR Surgical, and its release states no price or timetable for its option to buy CMR¹⁹. Cook Medical, a medical device maker, led Zenflow's funding round and agreed to distribute its implant, and its release states no exclusivity period or right to buy the company⁶⁸.

- 1 Ask for the option's price and expiry in writing.** Stryker's investment of about \$400 million comes with an exclusive option to buy all of CMR on agreed terms, which it may decline¹⁹.
- 2 Fix the exclusivity period.** Cook led Zenflow's \$52 million Series D (funding rounds are lettered in sequence) and agreed to become sole US distributor of its enlarged-prostate implant⁶⁸.
- 3 Name who leads outside the partner's territory.** CMR keeps the lead outside the US, and Stryker is to be its exclusive US sales agent¹⁹.
- 4 Ask what the stake buys and what it brings to your board.** Neither side said what share of CMR the \$400 million buys¹⁹.
- 5 Do not plan around the deal until it closes.** Stryker's transaction is subject to regulatory approvals and customary closing conditions¹⁹.

Model the case where the option is exercised. Boston Scientific invested \$1.5 billion for about 34% of MiRus and announced on 18 May 2026 an option to buy its heart valve business, whose valve was not cleared for sale in the US⁶⁹.

The option involves cash payments totalling \$3 billion after MiRus meets clinical and regulatory milestones⁶⁹.

APPLIES TO YOU IF Founders

a larger company has offered to invest in your start-up and sell its product.

Medtech buyers agreed to pay \$240 million to \$2.1 billion this month, and each deal shows what they will pay for

An investor pricing an exit can set it against what buyers agreed to pay for device and diagnostics companies this month, each beside the buyer's reason. The range of \$240 million to \$2.1 billion and the revenue multiples are HealthSeed's calculation^{50,70,71}.

The multiples divide price by revenue and are not like for like, since two use expected revenue (forecast) and one uses actual revenue over the last twelve months (trailing revenue)^{50,70,71}.

1 STERIS buying Xodus Medical

\$2.1bn

What the buyer or an analyst said it adds: Consumables used in the operating room^{45,70}

Price agreed: \$2.1bn cash at closing, plus an earnout (a later payment, due only if the business meets set targets) of up to \$150m

Revenue multiple (our calculation): About 8.6 times expected 2026 revenue (forecast)

2 GE HealthCare buying SOFIE Biosciences

\$945m

What the buyer or an analyst said it adds: A footprint in the final, time-critical stage of US supply of PET tracers⁴⁶

Price agreed: \$945m cash

Revenue multiple (our calculation): None: no revenue stated

3 Labcorp buying BioReference assets from OPKO

\$722m

What the buyer or an analyst said it adds: Analysts: a differentiated prostate cancer test with a route to wider use^{29,48,71}

Price agreed: \$722m cash at closing, plus up to \$150m on 4Kscore revenue

Revenue multiple (our calculation): About 2.9 times expected first-year revenue (forecast)

4 Agilent buying Proscia

\$240m

What the buyer or an analyst said it adds: Analysts: a way into pathology software and cross-selling to existing customers^{28,50}

Price agreed: \$240m cash upfront, plus up to \$30m on milestones

Revenue multiple (our calculation): At most about 13.3 times trailing revenue

Labcorp's \$722m adjusts on the business's revenue at closing, so its multiple can move⁴⁷.

Terumo Neuro, a Terumo Corporation business that develops catheter-based technologies for neurovascular disorders, agreed to buy Arsenal Medical^{72,73}. Arsenal's product is not cleared for sale in the US⁷³. Hologic, a medical technology company focused on women's health, agreed to buy Reveal Genomics, maker of a breast cancer test^{74,75}. Neither buyer disclosed a price, so both purchases sit outside the range^{73,75}.

Purchases agreed before this month and completed in it are outside the range too. iRhythm, which provides heart monitoring, closed its purchase of VitalConnect on 5 October 2026 for \$237.5 million in cash plus up to 423,334 shares^{76,77}. iRhythm says VitalConnect adds monitoring of several vital signs beyond heart rhythm and creates opportunities in hospital, remote, and hospital-to-home care⁷⁸. The total agreed at signing in August was about \$287.5 million^{76,79}.

Use the multiples as a range with their bases stated, and ask which of these buyers would see a portfolio company as filling a gap.

APPLIES TO YOU IF
Investors

you are pricing the sale of a device or diagnostics company.

TOP LIST Investors • Established

Who invested in medical devices this month, from €15 million to \$250 million

An investor deciding where to put money next can see where others put theirs this month and why, in the lead investor's words. An established company can read the same list for the start-ups its peers back. In our count, five lead products in the table are cleared, approved, or CE marked in at least one market^{58,80,81,82,83}. Precision's brain implant is not cleared for sale in the US, and the electrode the FDA cleared is for temporary use^{84,85}.

The list holds rounds of at least ten million dollars or euros by device, diagnostics, and surgical companies. The list covers rounds announced from 22 September⁸⁹ to 19 October 2026⁸². The list is incomplete for the first days of that period, because our news collection failed then.

1 Precision Neuroscience brain implants

\$250m

What the lead investor is betting on: Co-lead Bill Ackman: neurotechnology will be central to the next generation of cures, treatments, and rehabilitation^{84,85,86}

\$250m Series D, co-led by Pershing Square, the Ackman Oxman Institute, and an undisclosed fund; 24 September

Lead product's regulatory status: Layer 7-T electrode FDA-cleared for temporary use under 30 days; the brain implant itself is not cleared for sale in the US

-
- 2 Medical Microinstruments (MMI)** Symani microsurgery robot **\$125m**
 What the lead investor is betting on: BioStar's Louie Cannon: MMI is what BioStar looks for, pointing to its results in cancer-related lymphoedema (swelling after cancer treatment)⁵⁸
 \$125m Series D, BioStar Capital; 8 October
 Lead product's regulatory status: FDA-authorised and CE marked
-
- 3 Anaconda Biomed** funnel catheters for stroke **\$56m**
 What the lead investor is betting on: Omega's Claudio Nessi: a next-generation solution for the large and growing ischaemic stroke (a blood clot blocks blood flow to the brain) market^{80,87}
 \$56m, Omega Funds; 23 September
 Lead product's regulatory status: ANA5 catheter CE marked; ANA catheter is not cleared for sale in the US
-
- 4 Zenflow** Spring implant for an enlarged prostate **\$52m**
 What the lead investor is betting on: Cook's DJ Sirota: a new first-line option with reversibility^{68,81,88}
 \$52m Series D, Cook Medical, which agreed to become its sole US distributor; 5 October
 Lead product's regulatory status: FDA approved, December 2025
-
- 5 ZAP Surgical Systems** ZAP-X radiosurgery **\$36m**
 What the lead investor is betting on: Catalio's Nicholas von Guionneau: conviction in a new wave of non-invasive radiosurgery⁸²
 \$36m, Catalio Capital Management; 19 October
 Lead product's regulatory status: FDA-cleared, 2017
-
- 6 UltraSight** cardiac ultrasound software **\$24m**
 What the lead investor is betting on: Alive's Dudi Klein: clinical evidence with a scalable commercial model⁸³
 \$24m Series B2, Alive HealthTech Growth Fund; 23 September
 Lead product's regulatory status: FDA-cleared; more than 10 commercial sites
-
- 7 Dialybrid** graft for dialysis access **€15m**
 What the lead investor is betting on: None published; XGEN said only that it looks forward to supporting the company⁸⁹
 €15m Series A, XGEN Venture; 22 September
 Lead product's regulatory status: None stated
-

In our reading, most published bets point at something already visible, such as MMI's results in lymphoedema or the size of the stroke market^{58,80}.

Some of these rounds carry money or support from strategic companies, so an established company can see which start-ups its peers are backing^{58,68,82}. MMI's round includes an undisclosed strategic corporate investor⁵⁸. ZAP's round had continued support from Baheal, its strategic partner in China⁸².

APPLIES TO YOU IF you invest in device companies or are raising a round, or your company
Investors · Established tracks which start-ups its peers back.

COMPANY FEATURE Established

Europe now judges some devices once for every country, and one of the first two picked shows the question a company's evidence must answer

A maker of a high-risk device may now face one EU-level review of its clinical evidence, called a joint clinical assessment, measured against treatments chosen at that level⁹³. SAPIEN M3, a mitral heart valve replacement placed by catheter, is one of two devices in the European Commission's first selection of devices for joint clinical assessment, announced on 6 October 2026^{90,92}. SAPIEN M3's FDA approval was supported by a trial with no comparison group^{14,91,94}.

Step	What happened
1 ^{13,90}	CE mark, 14 April 2025
2 ^{14,91,94}	FDA approval announced 23 December 2025, supported by ENCIRCLE, a single-arm trial, which means every patient received the device
3 ⁹²	Recommended for joint clinical assessment at a June meeting of the member states' coordination group on health technology assessment
4 ⁹²	The Commission announced on 6 October 2026 that it had selected SAPIEN M3 as one of two devices
5 ⁹³	The developer's dossier (the evidence file) is due within 100 days, and the Commission does not say when the days start

THE DEVICE

SAPIEN M3

A mitral heart valve replacement placed by catheter, Edwards^{13,90}

CE MARK

14 April 2025¹³

FDA APPROVAL ANNOUNCED

23 December 2025¹⁴

MAIN TRIAL

ENCIRCLE, single-arm⁹¹

SELECTED FOR JOINT CLINICAL ASSESSMENT

6 October 2026⁹²

Class IIb and III, the EU's highest-risk device classes, can be selected once the EU's expert panel for that kind of device has given a scientific opinion on the device; not every such device is assessed⁹³. Each member state still decides nationally, using the joint assessment report⁹².

Our reading is that a single-arm trial gives assessors no direct comparison with the treatments chosen at EU level^{93,94}. ENCIRCLE's main group of 299 patients was unsuitable for other treatment options, so what the device is compared against would remain an open question⁹⁴.

As at 22 October 2026, how assessors treat a single-arm dossier is not yet known, since the Commission said on 6 October 2026 that joint work on devices was only beginning⁹².

APPLIES TO YOU IF

you make a Class IIb or III device and the main trial behind your approval has no comparison arm.

FOR

Established companies

BOX**Lessons · Founders****What this month's cash shortfalls teach a founder about timing a raise to a milestone**

In our reading, a raise sized to one milestone date leaves a founder short when that date moves. NanoEcho, a diagnostics developer, moved its planned approval application to the second half of 2029 and went bankrupt on 12 October 2026^{95,96,97}.

- 1 Plan for the date slipping.** NanoEcho moved the date in March 2026^{95,96}. In our reading, a raise sized only to the planned date leaves no room when the date moves, so size yours to a later date than your timetable shows.
- 2 Open the next raise early.** CRV, a venture firm, says a raise should open with 12 to 18 months of cash left⁹⁸. A prosecutor's appeal suspended a court-approved sale of IntegraGen, a genomics services firm^{99,100,101}.

APPLIES TO YOU IF
Founders

your next raise is sized to reach a milestone date.

ABOUT HEALTHSEED

HealthSeed is a Swiss healthcare venture studio and commercialisation partner. We work alongside biotech, medtech, diagnostics, digital health, and AI companies as they enter and scale across Europe, the United States, and the Middle East and North Africa, backed by an Expert Community of more than 35 specialists and a network of partners who have run the functions they advise on. We also build ventures and AI products of our own, so we read this market as participants. Vital Signs is where we publish what we are reading and what we think it means, with a primary source behind every claim.

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Sources

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4 Novocure (Form 8-K, Exhibit 99.1). The FDA approved Optune Pax for adults with locally advanced pancreatic cancer with gemcitabine and nab-paclitaxel; Novocure announced it on 11 February 2026. 2026-02-11. <https://www.sec.gov/Archives/edgar/data/1645113/000164511326000010/paxfdadecisionpr.htm>

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6 MedTech Dive (interview). Massimiliano Colella, chief executive of CMR Surgical, said he halted the planned US launch of first-generation Versius as his first decision, and called the US a market where CMR cannot afford a single mistake. 2026-03-04. <https://www.medtechdive.com/news/inside-cmr-surgical-pivot-before-us-robot-launch/813677/>

7 HealthSeed calculation. DBLG2 went from CE marking to FDA clearance in about 4.5 months, and the FDA review took about 8.2 months from receipt. 2025-08-04. <https://www.diabeloop.com/media-press/press-releases/diabeloop-obtains-ce-mdr-certification-for-dblg2>

8 Medtronic. Medtronic announced FDA clearance and a CE mark for its Affera Prism-2 mapping software in the same release, on 30 September 2026. 2026-09-30. <https://news.medtronic.com/2026-09-30-Medtronic-announces-regulatory-milestones-for-newest-cardiac-mapping-and-ablation-software>

9 US Food and Drug Administration (510(k) database). The FDA cleared DBLG2 by 510(k) K251152 on 19 December 2025, having received the submission on 14 April 2025, before the CE marking. 2025-12-19. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K251152>

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11 Intuitive Surgical (Form 10-Q, Q3 2026). In January 2026 the FDA cleared da Vinci 5 for selected thoroscopically-assisted cardiac procedures using non-force feedback instruments. 2026-10-21. <https://www.sec.gov/Archives/edgar/data/1035267/000103526726000071/isrg-20260930.htm>

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13 Edwards Lifesciences (Business Wire release, Nasdaq copy). Edwards announced a CE mark for the SAPIEN M3 transcatheter mitral valve replacement system on 14 April 2025, for symptomatic mitral regurgitation. 2025-04-14. <https://www.nasdaq.com/press-release/edwards-sapien-m3-receives-ce-mark-becoming-worlds-first-transcatheter>

14 Edwards Lifesciences. Edwards announced FDA approval of SAPIEN M3 on 23 December 2025, the first transcatheter therapy using a transseptal approach to be FDA approved for mitral regurgitation. 2025-12-23. <https://ir.edwards.com/news/news-details/2025/FDA-Approves-Edwards-Lifesciences-SAPIEN-M3-Mitral-Valve-Replacement-System-as-First-Transseptal-Transcatheter-Therapy/default.aspx>

15 Haemonetics (Form 8-K, Exhibit 99.1). Vivasure submitted its US PMA application for PerQseal Elite arterial closure in 2025, and Haemonetics announced its acquisition of Vivasure, a Galway, Ireland company, on 9 January 2026. 2026-01-09. <https://www.sec.gov/Archives/edgar/data/313143/000031314326000003/ex991-pressrelease192026.htm>

16 Vitestro (About us page). Aletta received CE mark approval in August 2024. undated. <https://vitestro.com/about-us/>

17 US Food and Drug Administration (510(k) database). The FDA cleared Inera Therapeutics' CLEAR Aspiration System by 510(k) K253404 on 24 June 2026, having received the submission on 30 September 2025. 2026-06-24. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K253404>

18 Inera Therapeutics (PR Newswire). Inera announced the 510(k) clearance on 28 September 2026; the cleared use is removal of fresh, soft emboli and thrombi from the peripheral arterial and venous systems. 2026-09-28. <https://www.prnewswire.com/news-releases/inera-therapeutics-inc-receives-us-fda-510k-clearance-for-the-clear-aspiration-system-featuring-cyclical-aspiration-302891209.html>

19 Stryker. Stryker will make a preferred equity investment of approximately \$400 million (£300 million) in CMR Surgical, the Cambridge, England maker of the Versius soft-tissue surgical robot. 2026-10-12. <https://investors.stryker.com/press-releases/news-details/2026/Stryker-and-CMR-Surgical-announce-strategic-alliance-to-advance-robotic-assisted-surgery/default.aspx>

20 CMR Surgical (release, BioSpace copy). The FDA cleared Versius Plus by 510(k) for cholecystectomy on 16 December 2025 (K252111), and CMR announced it the same day. 2025-12-16. <https://www.biospace.com/press-releases/cmr-surgical-secures-510k-clearance-of-its-versius-plus-robotic-surgical-system>

21 Stryker and CMR Surgical (joint release). Stryker becomes exclusive US sales agent for the Versius portfolio, while CMR continues to lead development and commercialisation outside the United States. 2026-10-12. <https://www.stryker.com/us/en/about/news/2026/stryker-cmr-surgical-announce-strategic-alliance-advance-robotic-assisted-surgery.html>

22 US Food and Drug Administration, Center for Devices and Radiological Health. The FDA's De Novo classification request is a marketing pathway to classify a novel medical device into class I or class II where there is no legally marketed predicate device. 2025-09-30. <https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/de-novo-classification-request>

23 NAMSA. NAMSA, a device consultancy, advises letting device economics decide launch order, saying high-cost devices that need the US commercial environment are often better served pursuing a PMA first and using US traction to enter Europe. 2026-10-21. <https://namsa.com/resources/blog/eu-mdr-vs-fda-medical-device-market-strategy/>

24 Boston Consulting Group. In a 2022 study by BCG and UCLA Biodesign, in which UCLA Biodesign surveyed more than 100 senior medtech executives, 89% of companies said they would prioritise US regulatory approval going forward. 2022-03-11. <https://www.bcg.com/publications/2022/us-ahead-in-medtech-regulation>

25 MedTech Europe (response to the Commission's public consultation on the targeted evaluation of the MDR and IVDR). MedTech Europe reports from its 2024 regulatory survey that, since the MDR date of application, the EU as choice for initial market fell 33% for large and 19% for small device companies. 2025-03-20. https://www.medtecheurope.org/wp-content/uploads/2025/03/250320_medtech_europe_input_for_questionnaire_t_e_submitted.pdf

26 European Commission (Public Health, medical devices new regulations overview page). The EU Medical Device Regulation, Regulation (EU) 2017/745, applies from 26 May 2021, after Regulation (EU) 2020/561 postponed its date of application by one year. 2024-07-31 (page last updated 2026-07-06). https://health.ec.europa.eu/medical-devices-new-regulations/overview_en

27 Reuters (syndicated by KSL.com). Steven Etoch, analyst, Stephens, said STERIS's Xodus purchase is a logical tuck-in that adds operating-room supplies, and that STERIS may be able to lift Xodus sales through its larger sales network and established relationships with hospital operating rooms. 2026-10-12. <https://www.ksl.com/article/51635307/steris-buys-surgical-products-maker-xodus-medical-for-21-billion>



28 MedTech Dive. Evercore ISI analysts (not named) said Agilent's purchase of Proscia is a small deal in the overall scheme of things that fits Agilent very well, gives Agilent entry to digital pathology at a lower price point, and lets it start cross-selling Proscia's software to its existing Dako customers at once. 2026-10-14. <https://www.medtechdive.com/news/agilent-to-buy-proscia-for-240m/832933/>

29 MedTech Dive. Evercore ISI analysts (not named) said 4Kscore adds a differentiated asset that Labcorp can take to wider adoption through its national commercial reach; William Blair analysts (not named) called 4Kscore a particularly compelling asset that could help avoid unnecessary biopsies. 2026-10-15. <https://www.medtechdive.com/news/labcorp-to-buy-bioreference-assets-for-up-to-872m/833116/>

30 STERIS (company overview page). STERIS, a global provider of products and services that support patient care, with an emphasis on infection prevention. undated (page footer: (c) 2026 STERIS). <https://www.steris.com/about>

31 STERIS plc (Form 8-K, SEC). STERIS agreed on 11 October 2026 to buy Xodus Medical, a Pennsylvania specialty surgical products business, for \$2.1bn in cash at closing, subject to adjustments. 2026-10-13. <https://www.sec.gov/Archives/edgar/data/1757898/000119312526420487/d165776d8k.htm>

32 Stephens Inc. (About Us page). Stephens, a family-owned financial services firm headquartered in Little Rock, whose services include investment banking and research. undated (page footer: 2026 Stephens Inc.). <https://www.stephens.com/about-us/>

33 Medtronic plc (Form 10-K, SEC). Medtronic's net sales were \$36.4bn in the fiscal year ended 24 April 2026, above the \$1bn threshold. 2026-06-18. <https://www.sec.gov/Archives/edgar/data/1613103/000162828026044354/mdt-20260424.htm>

34 Johnson & Johnson (Q3 2026 earnings release, 8-K exhibit 99.1, SEC). J&J MedTech sales were \$8.64bn in Q3 2026, up 2.5% on Q3 2025. 2026-10-13. <https://www.sec.gov/Archives/edgar/data/200406/000020040626000189/a2026q3exhibit991.htm>

35 Siemens Healthineers (press release). Siemens Healthineers' revenue was around EUR 23.4bn in fiscal 2025, which ended 30 September 2025. 2025-11-05. <https://www.siemens-healthineers.com/press/releases/2025q4>

36 STERIS plc (Form 10-K, SEC). STERIS's revenue was \$5.94bn in the fiscal year ended 31 March 2026. 2026-05-29. <https://www.sec.gov/Archives/edgar/data/1757898/000162828026039136/ste-20260331.htm>

37 GE HealthCare Technologies Inc. (Form 10-K, SEC). GE HealthCare's revenue was \$20.6bn in 2025. 2026-02-04. <https://www.sec.gov/Archives/edgar/data/1932393/000193239326000007/gehc-20251231.htm>

38 Agilent Technologies, Inc. (Form 10-K, SEC).

Agilent's revenue was \$6.95bn in the fiscal year ended 31 October 2025. 2025-12-22. <https://www.sec.gov/Archives/edgar/data/1090872/000109087225000087/a-20251031.htm>

39 Labcorp Holdings Inc. (Form 10-K, SEC). Labcorp's revenue was \$13.95bn in 2025. 2026-02-24. <https://www.sec.gov/Archives/edgar/data/920148/000092014826000111/lh-20251231.htm>

40 Medtronic (press release). Medtronic announced on 15 October 2026 that it had completed the separation of MiniMed Group, Inc. 2026-10-15. <https://news.medtronic.com/2026-10-15-Medtronic-Completes-Separation-of-Mini-Med-Group,-Inc>

41 MiniMed Group, Inc. (8-K exhibit 99.1, SEC).

Medtronic completed the separation by exchange offer, taking back 55,032,401 of its own shares for its remaining 252,813,348 MiniMed shares; the offer was 5.4 times subscribed and no cash price was paid. 2026-10-15. https://www.sec.gov/Archives/edgar/data/0002062583/000110465926116441/tm2627653d1_ex99-1.htm

42 Medtronic (press release). MiniMed completed its initial public offering in March 2026. 2026-09-14. <https://news.medtronic.com/2026-09-14-Medtronic-Launches-Exchange-Offer-to-Complete-Separation-of-MiniMed-Group,-Inc>

43 Siemens Healthineers (press release). Siemens Healthineers stopped selling general imaging ultrasound systems, including the Acuson Sequoia, Redwood, Juniper, and Maple, from 12 October 2026. 2026-10-12. <https://www.siemens-healthineers.com/press/releases/ultrasound>

44 Johnson & Johnson (Q3 2026 prepared remarks).

Joseph Wolk, Executive Vice President and Chief Financial Officer of J&J, said J&J is leaning towards a spin-off as the best option for long-term shareholder value, and that a spin has always been the base plan. 2026-10-13. <https://www.jnj.com/media-center/press-releases/johnson-johnson-q3-2026-earnings-ceo-and-cfo-prepared-remarks>

45 STERIS plc (release via GlobeNewswire). Dan Carestio, President and Chief Executive Officer, STERIS, said the Xodus Medical portfolio complements and expands the STERIS offering, particularly by adding consumables used in the operating room, and that Xodus has shown it can grow at double-digit rates. 2026-10-12. <https://finance.yahoo.com/healthcare/articles/steris-expands-healthcare-consumables-offering-120000298.html>

46 GE HealthCare (press release). GE HealthCare agreed to buy SOFIE Biosciences for \$945m in cash, announced 5 October 2026. 2026-10-05. <https://www.gehealthcare.com/en-us/about/newsroom/press-releases/ge-healthcare-to-acquire-sofie-biosciences-establishing-a-final-mile-footprint-for-pet-radiopharmaceutical-supply-in-the-us>



47 OPKO Health, Inc. (Form 8-K, SEC). Labcorp agreed to pay OPKO \$722m in cash at closing for select BioReference assets, adjusted for the business's revenue at closing. 2026-10-15. <https://www.sec.gov/Archives/edgar/data/944809/000119312526422877/opk-20261014.htm>

48 OPKO Health and Labcorp (joint press release, OPKO site). 4Kscore is an FDA-approved blood test that helps predict the likelihood of finding aggressive prostate cancer. 2026-10-15. <https://www.opko.com/investors/news-events/press-releases/detail/552/labcorp-enters-into-agreement-with-opko-health-to-acquire-select-asset-s-of-bioreference-health>

49 Agilent Technologies (press release boilerplate, About Agilent Technologies). Agilent Technologies, a company supplying analytical and clinical laboratory technologies, including instruments, software, and services. 2026-10-13. <https://investor.agilent.com/news-and-events/news/news-details/2026/Agilent-to-Acquire-Proscia-Advancing-AI-Enabled-Digital-Pathology-and-Scientific-Intelligence/default.aspx>

50 Agilent Technologies (release posted by Proscia). Agilent agreed on 13 October 2026 to buy Proscia, a digital pathology software provider, for \$240m in cash at closing and up to \$30m more on future performance milestones (up to \$270m). Proscia's trailing twelve-month revenue exceeded \$18m. Agilent expects to close early in its fiscal 2027, which starts 1 November. CEO Padraig McDonnell said the deal establishes a platform for scientific intelligence in tissue-based precision medicine. 2026-10-13. <https://proscia.com/press-release/agilent-to-acquire-proscia-advancing-ai-enabled-digital-pathology-and-scientific-intelligence>

51 MedTech Dive. Rachel Ellingson, Chief Strategy and Corporate Development Officer, Solventum, said selling its purification and filtration business to Thermo Fisher for about \$4.1bn paid down debt and funded a wound-care purchase; she does not expect large-scale consolidation because tuck-ins sit closer to the core and carry less risk, and said leaders should ask whether they are the right owner of a unit that is not getting the resources it needs. 2026-10-21. <https://www.medtechdive.com/news/expect-more-tuck-in-ma-portfolio-pruning-in-medtech-execs-say/833547/>

52 Solventum (8-K exhibit 99.1, SEC). Solventum announced on 5 August 2026 its intention to separate its Health Information Systems business, which had \$1.4bn in annual sales. 2026-08-05. https://www.sec.gov/Archives/edgar/data/0001964738/000196473826000043/solv_prxhis-separationannou.htm

53 A.E. Cooper Medtech Ventures. A.E. Cooper Medtech Ventures wrote in its Investor Notes Q3 2026 (deal data to 30 September 2026) that a divestiture does not necessarily signal technological failure, that a smaller dedicated owner may pursue a narrower clinical and regulatory strategy, and that acquirers are buying discrete capabilities to strengthen platforms they already own. 2026-10. <https://medtechmanda.com/investor-notes-q3-2026>

54 Johnson & Johnson (Form 10-Q, SEC). J&J's Orthopaedics business (DePuy Synthes) had Q3 2026 sales of \$2.345bn, up 3.2%. 2026-10-21. <https://www.sec.gov/Archives/edgar/data/200406/000020040626000197/jnj-20260927.htm>

55 Integer Holdings. KKR agreed to acquire Integer Holdings, a medical device contract development and manufacturing organisation, for \$127 a share in cash, an enterprise value of about \$5.7bn, announced 3 August 2026 after a strategic review announced 30 April 2026. The HSR waiting period was terminated early on 30 September 2026, and Integer stockholders approved the merger on 21 October 2026; close is expected by the end of 2026, subject to remaining closing conditions including regulatory approvals. 2026-08-03. <https://investor.integer.net/news-events/press-releases/news-details/2026/Integer-to-Be-Acquired-by-KKR-in-Transaction-Value-d-at-Approximately-5-7-Billion/default.aspx>

56 Irving Levin Associates (LevinPro HC), GlobeNewswire. LevinPro HC data show KKR's \$5.7bn acquisition of Integer Holdings was the private equity healthcare deal with the largest purchase price in Q3 2026. 2026-10-21. <https://www.globenewswire.com/news-release/2026/10/21/3385837/0/en/private-equity-investments-in-healthcare-fall-in-q3-26-according-to-data-from-levinpro-hc.html>

57 Archives of Plastic Surgery (Thieme), via PubMed Central. A systematic review in Archives of Plastic Surgery covered seven studies of robotic lymphatic supermicrosurgery with 134 patients and 221 anastomoses, 78 per cent of them done robotically; Symani was the most used system. 2026-05-29. <https://pmc.ncbi.nlm.nih.gov/articles/PMC13287940/>

58 MMI (company release). Louie Cannon, MD, founder and senior managing director, BioStar Capital, said MMI represents the pinnacle of what BioStar looks for, a transformational medical technology, and that MMI is already demonstrating this in cancer-related lymphedema. 2026-10-08. <https://www.mmimicro.com/blog/2026/10/08/mmi-series-d-raises-125m/>



59 Intuitive. In January 2026 the FDA cleared da Vinci 5 for nine selected thoroscopically assisted cardiac procedures, including mitral and tricuspid valve repair, mitral valve replacement and left atrial appendage closure. 2026-01-26. <https://isrg.intuitive.com/news-releases/news-release-details/da-vinci-5-cleared-cardiac-procedures>

60 Intuitive. Intuitive's da Vinci 5 received CE mark approval for adult cardiac surgery in Europe, including thoroscopically assisted cardiomy and minimally invasive coronary artery bypass procedures. 2026-09-22. <https://www.intuitive.com/en-gb/about-us/newsroom/da-vinci-5-receives-ce-mark-for-cardiac-procedures>

61 Tampa Bay Business and Wealth. Nicholas Panetta, chief of the Tampa General Hospital Plastic and Burn Surgery Institute, said Symani robotic microsurgery lets surgeons treat disease with an accuracy and precision that leads to better outcomes. 2026-07-01. <https://tbbwma.com/2026/07/01/robot-assisted-lymphatic-microsurgery/>

62 US Food and Drug Administration. Versius is cleared in the US only for cholecystectomy (gallbladder removal) in adults 22 and older; the Versius Plus version was cleared on 16 December 2025 (K252111) with the same indication as the 2024 De Novo. 2025-12-16. https://www.accessdata.fda.gov/cdrh_docs/pdf25/K252111.pdf

63 Medtronic. Medtronic's Hugo system is cleared in the US for urologic procedures only, and Medtronic says it is progressing plans to extend Hugo to general and gynaecologic surgery. 2026-09-16. <https://news.medtronic.com/2026-09-16-Medtronic-announces-FDA-clearance-for-LigaSure-TM-RAS-Maryland-instrument-on-the-Hugo-TM-RAS-system>

64 Medtronic. Medtronic announced on 3 December 2025 that the FDA cleared the Hugo robotic-assisted surgery system for urologic surgical procedures. 2025-12-03. <https://news.medtronic.com/2025-12-03-Medtronic-announces-FDA-clearance-of-Hugo-TM-robotic-assisted-surgery-system-for-urologic-surgical-procedures>

65 Medtronic. Medtronic announced on 3 June 2026 that it had submitted 510(k) filings to the FDA to extend Hugo to a general surgery indication, including hernia repair, and a gynaecologic surgery indication. 2026-06-03. <https://news.medtronic.com/2026-06-03-Medtronic-submits-510-k-filings-to-expand-Hugo-TM-robotic-assisted-surgery-system-into-general-and-gynecologic-specialties-in-the-United-States>

66 MMI (Medical Microinstruments). On 30 July 2026 the FDA approved a supplement to MMI's investigational device exemption for REMIND, an early feasibility study of Symani in Alzheimer's disease, allowing enrolment to expand to 15 patients; the use remains investigational. 2026-07-30. <https://www.mmimicro.com/blog/2026/07/30/remind-phase-ii-enrollment/>

67 Johnson & Johnson. Johnson & Johnson announced on 22 July 2026 that the FDA granted De Novo authorisation for its OTTAVA robotic surgical system for general surgery procedures including Roux-en-Y gastric bypass, gastrectomy, cholecystectomy and hiatal hernia repair; it will launch with select US customers, and a US inguinal hernia trial is ongoing. 2026-07-22. <https://www.jnj.com/media-center/press-releases/johnson-johnson-receives-fda-market-authorization-in-the-u-s-for-its-ottava-robotic-surgical-system>

68 Cook Medical (press release boilerplate, About Cook Medical). Cook Medical, a medical device maker headquartered in Bloomington, Indiana. 2026-10-05. <https://www.cookmedical.com/newsroom/zenflow-distributor/>

69 Boston Scientific. Boston Scientific invested \$1.5 billion in MiRus LLC, maker of the investigational SIEGEL TAVR heart valve, for an approximately 34% equity stake. 2026-05-18. <https://news.bostonscientific.com/2026-05-18-Boston-Scientific-announces-strategic-investment-in-MiRus-LLC>

70 HealthSeed calculation. STERIS is paying about 8.6 times Xodus's expected 2026 revenue at the \$2.1bn closing price, and about 7.3 times net of tax benefits (our calculation). 2026-10-12. <https://sterisplc.gcs-web.com/news-releases/news-release-details/steris-expands-healthcare-consumables-offering-definitive/>

71 HealthSeed calculation. Labcorp is paying about 2.9 times the first-year revenue it expects from the BioReference assets (our calculation). 2026-10-15. <https://www.labcorp.com/education-events/press-releases/labcorp-enters-agreement-opko-health-acquire-select-assets>

72 Terumo Neuro (About Us page). Terumo Neuro, a Terumo Corporation business that develops catheter-based, minimally invasive technologies for treating neurovascular disorders. undated (page footer: (c)2026 Terumo Neuro). <https://www.terumoneuro.com/about-us>

73 Terumo Neuro (GlobeNewswire release, syndicated by The Manila Times). Terumo Neuro agreed to acquire Arsenal Medical, a clinical-stage company developing NeoCast, an investigational liquid embolic for chronic subdural hematoma, in a release dated 29 September 2026. 2026-09-29. <https://www.manilatimes.net/2026/09/30/tmt-newswire/globenewswire/terumo-neuro-signs-agreement-to-acquire-arsenal-medical-advancing-next-generation-liquid-embolic-innovation-for-treating-chronic-subdural-hematoma-csdh/2435756>

74 Hologic (press release boilerplate, About Hologic, Inc.). Hologic, a medical technology company focused on women's health. 2026-10-19. <https://www.hologic.com/about/press-release/hologic-signs-definitive-agreement-acquire-reveal-genomics>



75 Hologic (Business Wire). Hologic signed a definitive agreement to acquire Reveal Genomics, maker of the HER2DX breast cancer test, announced 19 October 2026; no price was disclosed and completion is subject to Spanish regulatory approval. 2026-10-19. <https://finance.yahoo.com/healthcare/articles/hologic-signs-definitive-agreement-acquire-193000329.html>

76 iRhythm Technologies (Exhibit 99.1 to Form 8-K). iRhythm completed its purchase of VitalConnect on 5 October 2026 for \$237.5m in cash, subject to customary adjustments, plus up to 423,334 shares issued at closing; the 6 August 2026 signing release put total consideration at about \$287.5m, about \$50m of it in stock. iRhythm says the deal adds mobile cardiac telemetry and multi-vitals monitoring, extends it into inpatient, remote and hospital-to-home settings, and should lift its revenue growth from 2027 while keeping its 15% adjusted EBITDA margin target for 2027. VitalConnect revenue is not disclosed. 2026-10-05. https://www.sec.gov/Archives/edgar/data/0001388658/000138865826000083/vitalconnect_closingprxf.htm

77 iRhythm Holdings (SEC Form 8-K, exhibit 99.1). iRhythm completed its acquisition of VitalConnect on 5 October 2026. 2026-10-05. https://www.sec.gov/Archives/edgar/data/1388658/000138865826000083/vitalconnect_closingprxf.htm

78 iRhythm Holdings, Inc. (GLOBE NEWSWIRE). iRhythm said at signing that VitalConnect's biosensor platform can monitor up to 11 physiological parameters, extending its multi-vitals strategy beyond traditional ambulatory cardiac monitoring, and that the combination creates additional opportunities in inpatient monitoring, remote patient monitoring, and hospital-to-home care. 2026-08-06. <https://investors.irhythmtech.com/news/news-details/2026/iRhythm-to-Acquire-VitalConnect-Expanding-Its-Cardiac-Monitoring-Platform-Across-Ambulatory-Inpatient-and-Hospital-to-Home-Care/default.aspx>

79 iRhythm Holdings (Form 10-Q, SEC). iRhythm agreed consideration of \$287.5m for VitalConnect, \$237.5m in cash and \$50.0m in stock, subject to adjustments. 2026-08-06. <https://www.sec.gov/Archives/edgar/data/1388658/000138865826000072/irtc-20260630.htm>

80 Anaconda Biomed (company release). Anaconda's ANA5 Funnel Catheter is CE marked; the ANA Funnel Catheter is investigational in the US. 2026-09-23. <https://anaconda.bio/anaconda-biomed-secures-56-million-financing-from-new-and-existing-investors/>

81 Zenflow (company news page). The FDA approved the Zenflow Spring Implant and Delivery System for BPH in December 2025. 2025-12-11. <https://www.zenflow.com/news>

82 ZAP Surgical (company newsroom footer). ZAP-X received US FDA 510(k) clearance in 2017. 2026-10-19. <https://zapsurgical.com/news/zap-surgical-secures-36-million-led-by-catalio-capital-management/>

83 UltraSight (company release). UltraSight's software has FDA 510(k) clearance to assist cardiac ultrasound scans and is deployed at more than 10 commercial sites. 2026-09-23. <https://ultrasight.com/ultrasight-raises-24-million-to-scale-its-ai-guided-cardiac-workflow-platform-across-u-s-health-systems/>

84 Precision Neuroscience (company news page, linking its GlobeNewswire release). Precision Neuroscience closed an oversubscribed \$250 million Series D, co-led by Pershing Square Inc., the Ackman Oxman Institute, and a life sciences investment fund it did not name; announced 24 September 2026. 2026-09-24. <https://precisionneuro.io/articles>

85 US Food and Drug Administration (510(k) database; decision letter at https://www.accessdata.fda.gov/cdrh_docs/pdf24/K242618.pdf). The FDA cleared Precision's Layer 7-T cortical electrode through 510(k) K242618, with a decision dated 30 March 2025, for temporary use of less than 30 days in recording, monitoring, and stimulating signals on the brain surface. 2025-03-30. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K242618>

86 Precision Neuroscience (GlobeNewswire release, read on the BioSpace copy). Bill Ackman, CEO of Pershing Square, co-founder of the Ackman Oxman Institute and a co-lead investor in the round, said neurotechnology will be central to the next generation of cures, treatments, and rehabilitation. 2026-09-24. <https://www.biospace.com/press-releases/precision-neuroscience-closes-oversubscribed-250m-series-d-led-by-pershing-square-inc-the-ackman-oxman-institute-and-a-leading-life-sciences-investment-fund>

87 NHS (nhs.uk, Health A to Z). An ischaemic stroke happens when a blood clot blocks blood flow to the brain, and the NHS describes it as the most common type of stroke. 2024-09-12. <https://www.nhs.uk/conditions/stroke/diagnosis/>

88 Zenflow (GlobeNewswire release). DJ Sirota, Senior Vice President, MedSurg Division, Cook Medical, said the Zenflow Spring System combines a new first-line option with reversibility, and that its flexible cystoscope, implant sizes, and positioning balloon give a competitive advantage in the BPH category. 2026-10-05. <https://www.globenewswire.com/news-release/2026/10/05/3374449/0/en/zenflow-secures-52m-series-d-financing-and-announce-s-exclusive-us-distribution-partnership-with-cook-medical.html>



89 Diallybrid (release, copy on BioSpace). Diallybrid (Cantù, Italy) closed a €15 million Series A led by new investor XGEN Venture, with CDP Venture Capital (Rilancio Fund); announced 22 September 2026. 2026-09-22. <https://www.biospace.com/press-releases/diallybrid-secures-15-million-series-a-round-and-announces-successful-first-in-human-implant-of-novel-silkothane-arteriovenous-graft-for-vascular-access-in-hemodialysis>

90 Edwards Lifesciences. Edwards received the CE mark for SAPIEN M3 on 14 April 2025 and described it as the world's first transfemoral transcatheter mitral valve replacement system, for symptomatic moderate-to-severe or severe mitral regurgitation in patients deemed unsuitable for surgery or transcatheter edge-to-edge repair. 2025-04-14. <https://www.edwards.com/newsroom/news/2025-04-14-edwards-sapien-m3-receives-ce-mark-%2Dbecoming-world>

91 TCTMD (Todd Neale). TCTMD reported that the FDA's approval of SAPIEN M3 in December 2025 was supported by the results of the single-arm ENCIRCLE trial. 2026-10-16. <https://www.tctmd.com/news/edwards-pulls-some-lot-s-sapien-m3-delivery-system-fda-alert>

92 European Commission (DG SANTE). On 6 October 2026 the Commission announced it had adopted its first decision selecting medical devices for joint clinical assessment: two devices, both addressing cardiovascular disease, one of which is SAPIEN M3 from Edwards Lifesciences LLC; the page says the day marks the beginning of joint work on devices under the HTA Regulation. 2026-10-06. <https://ec.europa.eu/newsroom/sante/newsletter-archives/80023>

93 European Commission. Joint clinical assessment can cover Class IIb and III devices under the MDR where the relevant expert panel has given a scientific opinion, and Class D IVDs under the IVDR where the panel has given its views; not every device with such an opinion is assessed, and the Commission selects devices taking into account six criteria: unmet medical need, first-in-class status, potential impact on patients, public health or healthcare systems, incorporation of AI or machine learning, cross-border dimension, and potential Union-wide added value. undated page, latest update 2026-10-06. https://health.ec.europa.eu/health-technology-assessment/implementation-regulation-health-technology-assessment/joint-clinical-assessments-medical-devices-and-vitro-diagnostic-medical-devices_en

94 Edwards Lifesciences. ENCIRCLE, a single-arm pivotal trial, met all primary and secondary safety and effectiveness endpoints in its main cohort of 299 patients unsuitable for other treatment options, with 95.7% reaching mitral regurgitation grade 0 or 1+; one-year data were presented at TCT on 27 October 2025 and published in The Lancet. 2025-12-23. <https://www.edwards.com/newsroom/news/2025-12-23-fda-approves-edwards-lifesciences-%2Dsapien-m3-mitra>

95 NanoEcho AB (publ) (MFN regulatory release). On 12 October 2026 the board of NanoEcho AB, a Lund diagnostics developer, filed the company's own bankruptcy petition at Helsingborg District Court. 2026-10-12 08:13 CEST. https://nanoecho.se/mfn_news/nanoecho-ab-publ-ansoker-om-konkurs/

96 NanoEcho AB (publ) (MFN regulatory release). On 2 March 2026 NanoEcho's board, citing the continued difficult investment climate, updated the business plan and moved its planned application for marketing approval from the first to the second half of 2029. 2026-03-02 19:55 CET. https://nanoecho.se/mfn_news/nanoecho-ab-publ-offentliggor-utfall-i-foretradesemissionen/

97 NanoEcho AB (publ) (MFN regulatory release). Helsingborg District Court declared NanoEcho bankrupt on 12 October 2026 and appointed advokat Patrik Kalman of Trädgårdh Advokatbyrå, Malmö, as trustee. 2026-10-12 12:54 CEST. https://nanoecho.se/mfn_news/nanoecho-ab-publ-har-forsatts-i-konkurs/

98 CRV. CRV, a venture firm, says a raise should open with 12 to 18 months of runway left, and that a raise takes three to six months from first contact to close. 2026-08-18. <https://www.crv.com/content/startup-runway>

99 Euronext (IntegraGen regulated press release listing). On 12 October 2026 IntegraGen, a French genomics and bioinformatics services company listed on Euronext Growth Paris, announced the sale of its business and assets to ABL Diagnostics and its placement in judicial liquidation. 2026-10-12. <https://live.euronext.com/en/listview/company-press-release/170353>

100 IntegraGen SA (Business Wire regulatory release, republished). On 9 October 2026 the Evry commercial court approved the sale of IntegraGen's entire business to ABL Diagnostics, and IntegraGen was placed in judicial liquidation. 2026-10-12. <https://www.sustainabilityhq.com/integragen-annonce-la-cession-de-ses-activites-et-actifs-a-abl-diagnostics-et-son-placement-en-liquidation-judiciaire/>

101 ABL Texcell Diagnostics (Business Wire, republished by Yahoo Finance). The public prosecutor appealed the 9 October judgment; the appeal suspends it, and IntegraGen is back in judicial reorganisation pending the Paris Court of Appeal's decision. 2026-10-16. <https://finance.yahoo.com/healthcare/articles/abl-texcell-diagnostics-notice-appeal-151500167.html>





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