Vital Signs: MedTech

Devices, diagnostics, and surgical innovation

HealthSeed
HEALTHSEED INTELLIGENCE

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THIS EDITION'S SIGNAL

Every decision that mattered this cycle came after approval, from bodies applying their own test on their own calendar. France refused the market leader's newest heart valve. Britain opened NHS funding to a rival technology whose maker had just raised its capital for America.

Decided by a regulator

PREDICTABLE, PUBLISHED, BUDGETED

- Whether the device is safe
- Whether it performs as claimed
- Whether it may be placed on the market

Decided by someone else

NATIONAL, DISCRETIONARY, ON THEIR TIMETABLE

- What a health system will pay for it
- What a safety signal costs across markets
- Which requirements the next version must meet
- Whether a buyer believes your number

Vital Signs: MedTech is a briefing on devices, diagnostics, and surgical innovation from HealthSeed AG, published every two weeks. This is the first edition.

It is written for people carrying commercial responsibility in medical technology, expert in one corner of the field and generalist everywhere else. Someone building diagnostics has rarely filed a French reimbursement dossier. Where a term needs explaining, we explain it.

Every claim carries a source you can open. The HealthSeed Perspective blocks are our own read rather than reporting.

IN THIS EDITION

01 Reimbursement

Most device companies budget carefully for approval and treat reimbursement as the administrative step that follows it. The sequence runs the other way. Approval is the predictable part, with published requirements, a known cost, and a defined end. Reimbursement is a negotiation with a counterparty who has a fixed budget, no obligation to you, and a different question in mind.

This cycle produced two of those decisions in nine days, in two countries, pointing in opposite directions.

Eight decisions in one day

France's reimbursement authority is the Haute Autorité de Santé. Its device committee asks whether a product improves on what the country already pays for, and grades the answer on a five-point scale where the top grade is a major improvement and level five is none at all.

11 August 2026, CNEDiMTS	Grade	Outcome
Medtronic ONYX, embolisation implant	Level 5	Accepted
Abbott TRICLIP G5, tricuspid valve repair	Level 5	Accepted
Five further products, nebuliser to wound dressings	Level 5	Accepted
Edwards SAPIEN 3 Ultra RESILIA, transfemoral aortic valve	**Insufficient**	**Refused**

Seven products were accepted, and every one of the seven was graded level five. They ranged from an embolisation implant and a tricuspid valve repair system down to wound dressings. The same test, applied the same way, to an implant and to a dressing.

The eighth was refused. According to the HAS record for that date, Edwards Lifesciences' SAPIEN 3 Ultra RESILIA, the newest generation of the transcatheter aortic valve family Edwards leads worldwide, was found to have insufficient expected benefit for the listing it requested. HAS publishes the outcome without the reasoning, so the basis for the refusal is not on the public record and is recorded here as absent.

HAS CNEDiMTS opinions, 11 August 2026. The Edwards opinion is reported from the HAS record and was not independently confirmed at the time of writing.

Why France grades this way

A national reimbursement budget is finite and largely fixed in advance. Every euro committed to a new device is a euro unavailable elsewhere in the same system, which makes the relevant question narrower than it first appears. The committee is not asking whether a product works. It is asking whether paying more for it than for the incumbent buys the health system anything.

That framing explains the seven level-five gradings. Each of those products almost certainly works. None demonstrated that it works better than what France already funds, so France will fund them at the rate it already pays.

It also explains why market position offers no protection. A large installed base, a strong brand, and years of registry data all answer whether a product performs. None answers whether the new generation outperforms the old one, and that is the only question being asked.

Nine days later, Britain opened a category France had just closed

NICE published guidance HTG780 on 20 August supporting routine NHS funding for ex-situ machine perfusion, the technique of keeping a donor liver alive outside the body before transplant instead of packing it in ice. Four systems are named: OrganOx metra, XVIVO Liver Assist, Aferetica PerLife Pro, and Bridge to Life VitaSmart. The evaluation found the technology clinically beneficial and a cost-effective use of NHS resources.

France measured seven devices against products it already funds and found no improvement in any of them. Britain measured a category it had never funded and opened it. The distinction is not national temperament. A device entering an established category is measured against an incumbent, and a device creating a category has no incumbent to be measured against.

NICE HTG780, 20 August 2026. European Commission ongoing-JCA tracker, extracted 10 August 2026.

15 / 0

Assessments under way in the EU Joint Clinical Assessment tracker on 10 August, against medical devices and in-vitro diagnostics covered. All fifteen are medicines. Any plan resting on European HTA harmonisation reaching devices should be read against that. Every market you enter is a separate assessment, on a separate timetable, against a separate comparator.

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The refusal is the headline and the acceptances are the warning. A company braced for rejection has at least considered the possibility. Very few are braced for being listed at the incumbent rate, which is the far more common outcome and arrives looking like success.

Consider what that does to a plan. The commercial model assumed a premium over the previous generation. The sales narrative was built on being demonstrably better. The revenue forecast the board approved priced in both. A level-five grading invalidates the pricing, the narrative, and the forecast in a single published document, and it does so after the launch investment is committed and the field team is hired.

We have watched companies build a French dossier around real-world performance data that reads impressively and settles nothing about incremental benefit, because the comparator was their own previous product and the truthful answer was parity. The dossier was not weak. It answered a question nobody had asked.

Commission one analysis before you build the plan: what does this version do that our last version did not, stated in patient outcomes rather than product features? Give the answer to your commercial lead rather than your regulatory lead, because it is a pricing decision wearing regulatory clothing. A parity finding is survivable when you have priced for it from the start. Skip the analysis and the committee performs it for you, then publishes the result.

Applies to you if: you are taking a device into France, Germany, or Italy, where reimbursement turns on an added-benefit assessment. Applies most sharply if the product is the next generation of something you already sell.

02 Money

Two calendars decide what a medtech company can do over the next eighteen months. One is the funding calendar, which a founder and a board control and can accelerate or delay. The other is the assessment calendar, which belongs to national reimbursement bodies working through their own queues and publishing when they are ready. Companies plan against the first and are governed by the second.

A raise for one market, a decision in another

Bridge to Life closed 110 million dollars in Series C equity and debt on 12 August. Soleus Capital led the equity with Lauxera Capital Partners. The money is for building the United States field organisation behind VitaSmart, which has held FDA De Novo clearance since January 2026 and is the only hypothermic oxygenated perfusion system authorised in that country for liver transplantation.

Eight days later NICE named VitaSmart in the guidance covered in section one. The capital was raised for America. The route that opened was British.

Astorg separately completed the carve-out of Thermo Fisher's microbiology diagnostics business into a standalone company, at a value reported near 1.075 billion dollars. iRhythm agreed to acquire VitalConnect, which makes wearable cardiac monitors, for approximately 287.5 million dollars in cash and stock.

These three transactions run in two directions at once. Capital is arriving to scale newly cleared platforms, and a large strategic is shedding a diagnostics business it no longer wants inside the group. Both moves make sense from where each party sits, because a specialist owner will fund a diagnostics business through a rebuild that a diversified parent judges a poor use of group capital.

CORRECTION TO THE RECORD

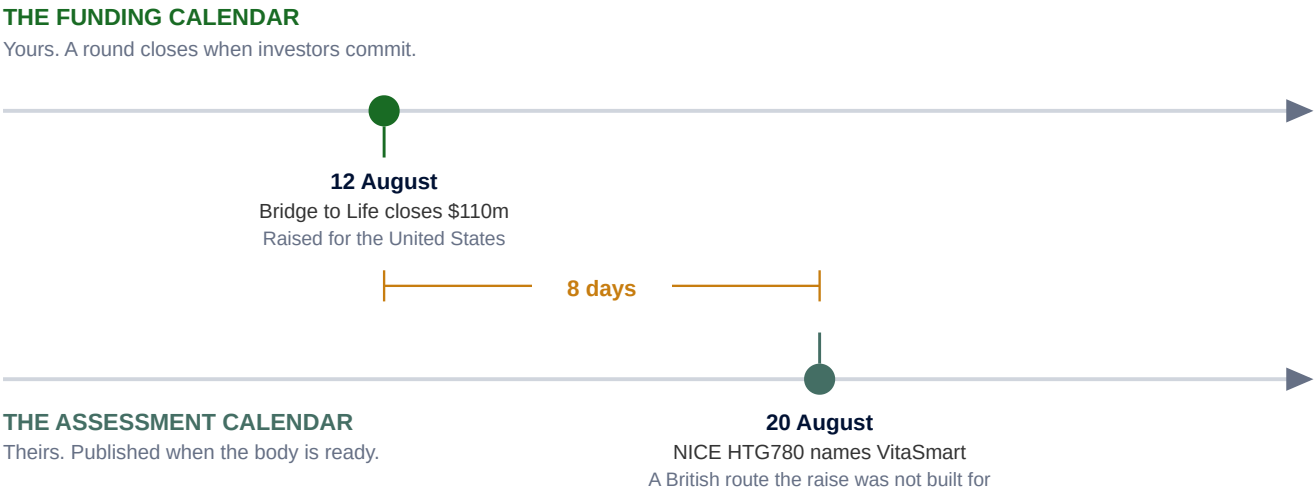
Siemens Healthineers Diagnostics. Reported on 12, 14, and 19 August to be in preliminary discussions with private equity about a sale, with Chinese procurement pressure and a laboratory platform migration given as the reasons.

No primary source confirmed it in any of those three reports, across a full two-week window.

If you are building a comparable set for a diagnostics valuation, this transaction is not evidence, and at least one published analysis has already treated it as though it were.

Bridge to Life announcement, 12 August 2026. FDA De Novo clearance, January 2026. Astorg completion announcement. iRhythm SEC filing, August 2026.

Two calendars, August 2026. Only one of them belongs to the company.



Why these clocks never align

Assessment bodies work from published workplans that queue technologies by clinical priority and evidence readiness, not by any company's commercial timing. NICE does not consult a manufacturer's cash position when scheduling an evaluation, and it does not publish a decision date the way a court publishes a hearing. A company learns the outcome when the guidance appears.

Funding works the opposite way. A round closes when investors commit, which is a date the company influences directly and often controls within a quarter.

Nothing about that is dysfunctional. It is how the system is built, and it means the plan you present at a board meeting always contains at least one date you cannot move.

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The number worth noticing in the Bridge to Life sequence is eight days, and nobody planned it. The company now holds capital committed to one geography and an open route in another, which is a good problem and still a problem. Field organisations are recruited against a market plan, and moving one costs a quarter that was never budgeted.

The reverse case is the one that damages companies, and it is far more common. A round is timed on the assumption that a positive assessment lands first, the assessment slips two quarters, and the company raises into a story it cannot yet evidence. That conversation with investors is materially harder than the one Bridge to Life is having.

When we sequence a raise for a company with live assessments running in parallel markets, we map the assessment calendar against the funding calendar before either is fixed, because those two clocks belong to different people. If you are raising now with a NICE, HAS, or G-BA process under way, put one slide in front of your board showing what the deployment plan looks like if the decision arrives early, and what it looks like if it arrives two quarters late. Both are live scenarios and only one of them is usually planned for.

Applies to you if: you are raising capital while any national assessment is in progress, or benchmarking a diagnostics valuation against reported comparables.

03 Vigilance

Getting a device approved is a project. It has a start, an end, a budget, and someone whose job finishes when it is done. Keeping a device on the market is not a project. It runs for as long as the product exists, it has no completion date, and in most companies under two hundred people nobody owns it exclusively.

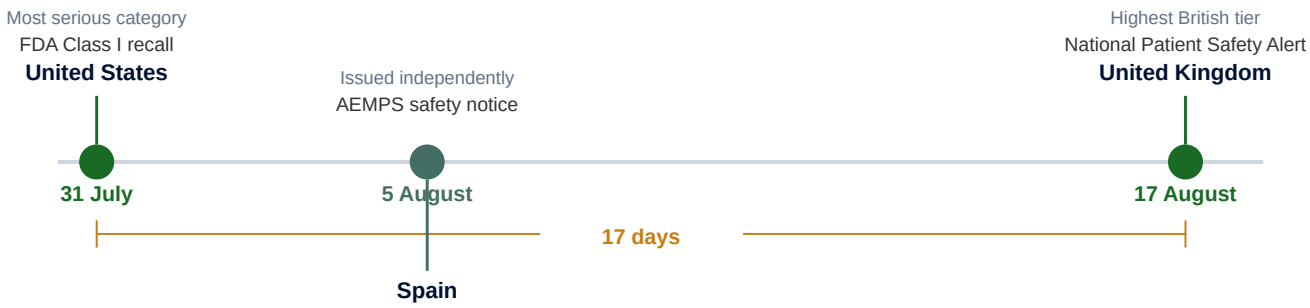
This cycle showed what that asymmetry costs when a fault appears.

One fault, three regulators, seventeen days

ResMed's Astral 100 and Astral 150 are ventilators used at home, by people who depend on them to breathe through the night. An internal supercapacitor can leak, and the leak can stop therapy.

Same device, same root cause, three regulators, seventeen days between the first action and the last. Nothing in the three notices indicates they were coordinated.

One supercapacitor fault, three regulators, seventeen days.



FDA recall database, 31 July 2026. AEMPS safety notice, 5 August 2026. MHRA National Patient Safety Alert, 17 August 2026.

Why they did not move together

European device regulation harmonised approval. A CE mark means the same thing in Lisbon and Helsinki, and that took two decades of work.

Vigilance was never harmonised to the same degree. Each national competent authority retains its own reporting formats, its own escalation tiers, its own deadlines, and its own decision about whether a fault warrants a notice, an alert, or nothing at all. EUDAMED will eventually carry some of this load, and it does not carry it yet.

So a company that built its regulatory function around getting products approved has built a function shaped for the harmonised problem, and vigilance is the unharmonised one. The mismatch stays invisible until a signal arrives, at which point one engineering fault becomes three separate remediation obligations, each with its own format, deadline, and evidence of completion, running on three clocks that nobody is synchronising for you.

7

Class I recalls from seven manufacturers in two weeks. Six further actions beyond ResMed came from Boston Scientific, Abiomed and Oscor, Hamilton Medical, Baxter, Becton Dickinson, and Medline, covering cardiovascular, respiratory, and vascular access devices. A heavy cycle rather than a pattern about any one company, and seven reminders that this is routine rather than exceptional.

FDA recall database, 11 to 24 August 2026.

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The cost of a multi-market safety signal is almost never modelled before it happens, and the remediation itself is the smaller part of it. The larger part is a quarter of senior engineering and regulatory attention that stops doing anything else, arriving without warning, in a company that had those people committed to the next release.

The uncomfortable part is that the ResMed sequence looks like a competent response rather than a failure. Three regulators acted, a life-support fault was contained, and no part of that suggests anything went wrong in the handling. Seventeen days is what a well-run cascade looks like. If your own plan assumes faster, the plan is wrong rather than ambitious.

Take one afternoon and write the answer for a single hypothetical fault in your highest-risk product. Which authorities must be told, in what format, inside how many days, and who signs each notice. Most companies discover during that exercise that the answer exists in one person's head and covers one market. Getting it onto paper costs an afternoon now. Assembling it during a live Class I action costs the quarter.

Applies to you if: you hold a CE mark and any second-market clearance, and have never written down what a safety signal would require of you in each.

04 Two device categories that did not exist last month

When a new kind of device reaches the American market, something happens that has nothing to do with that device. The FDA writes the rules for the category it has just created, and every product that follows is measured against rules shaped to fit the first one through. That makes a first authorisation a competitive event as much as a regulatory one. It happened twice this cycle.

Why De Novo is different from the other two routes

510(k)	Premarket approval	De Novo
Show the device is substantially equivalent to something already on the market. Fast and cheap, because the comparison does the work.	For high-risk devices. Requires clinical evidence and takes years.	For devices with no equivalent to compare against. Creates a new classification and writes the special controls every later product must meet.

Those controls are drafted around the device in front of the agency at the time. For the first company through, that is a durable advantage. For everyone following, it is a specification written to someone else's design.

Two of them, one month apart

OTTAVA, 21 July. The FDA granted De Novo authorisation to Johnson and Johnson's surgical robot, integrated into the operating table, cleared for nine named upper abdominal procedures from gastric bypass to hiatal hernia repair.

Aletta, 19 August. Vitestro's standalone robotic blood-draw device, authorised for supervised use with adults in outpatient settings. Blood draw is among the most frequently performed procedures in medicine and among the least automated, and Aletta is the first machine cleared to perform it without a phlebotomist's hands.

FDA De Novo database, July and August 2026.

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Two new classifications inside one cycle is unusual, and the consequence sits in the special controls rather than in the announcements. If you are building anything adjacent to either category, those documents are now the specification your submission will be measured against, and they were written to fit the first product through.

The cost of finding a gap late is specific and large. A control requiring a bench test your architecture cannot support is a design change, and a design change after design freeze is a rework cycle plus a revalidation, which in surgical robotics runs to quarters rather than weeks. The same gap found today is a decision about what to build.

Read both authorisations in full if you are anywhere near robotic surgery or laboratory automation, and ask whoever owns regulatory strategy one question: which of these controls can our current design meet, and which require a change we have not budgeted? Ask it before design freeze, because afterwards the answer costs a great deal more than the question.

Applies to you if: you are developing a device with no clear predicate, or building in surgical robotics or laboratory automation.

05 What counts as evidence

The question a hospital asks about new technology has changed. It used to be whether the thing works. Enough health systems have now been through two or three rounds of technology procurement, and enough of those purchases underdelivered, that the question has moved to whether the number in your deck can be trusted and who produced it.

Three numbers circulated this cycle, all describing technology working in hospitals, all sitting on different evidentiary footings, and all being used in the same procurement conversations.

Three numbers from one cycle, placed by how the evidence was produced.

INDEPENDENTLY AUTHORED, PEER-REVIEWED

7%

Rise in monthly surgical case volume at Houston Methodist, roughly 25 additional cases, without adding rooms, staff, or hours. Apella platform.

Authored independently of the company.

SURVEY FINDING

86 / 6

Percent of physicians seeing clinical value in wearable data, against percent who have integrated it into workflows. Six countries.

Cited by Oura's chief medical officer.

ORGANISATIONAL SELF-REPORT

41%

Increase in trial screening capacity across 47 hospitals. Ochsner Health and Paradigm.

Published by the parties that ran the deployment.

Houston Methodist study via Apella. Politico interview, August 2026. Ochsner Health announcement, August 2026.

Why the gap between 86 and 6 is the whole story

Those two figures describe a market where clinical belief has stopped being the constraint. Physicians have largely been persuaded, and what stands between that persuasion and actual use is integration into a workflow, a procurement process, a budget holder, and evidence a finance director will accept.

That reframes what a vendor is selling into. The buyer is rarely unconvinced about the technology. They are unconvinced that the number in front of them will survive contact with their own institution, because they have previously bought a number that did not.

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A self-reported figure carries no dishonesty and no weakness. It is simply a different kind of claim from an independently authored one, and a second-time buyer knows the difference even when the deck does not mark it.

Very few vendor decks state who produced their headline number. Stating it has therefore become a differentiator instead of a compliance exercise, which is an unusual position and unlikely to last, because the practice will spread.

The asymmetry is worth understanding. A buyer who is told a figure is self-measured discounts it modestly and moves on. A buyer who discovers it during diligence discounts the figure, the deck, and the company, and that discovery costs far more than the disclosure would have.

Look at whatever outcome figure sits in your own materials and write one line beside it naming who produced it, under what design, and with what independence. If you measured it yourself, say so in the deck. If you have a peer-reviewed result, put the citation on the slide rather than in an appendix, because it is doing more work than any adjective you could put next to it.

Applies to you if: your commercial materials carry an adoption, efficiency, or outcome figure.

Critical deadlines

Date	What closes or begins	Who it reaches
28 Sep 2026	EMA CTIS Annual Safety Report module goes live, mandatory	Sponsors running a trial under the EU Clinical Trials Regulation
13 Oct 2026	Comment period closes on the CMS RAPID coverage pathway	Device makers seeking US Medicare coverage
16 Oct 2026	Comment deadlines close on FDA reclassification proposals for digital breast tomosynthesis and seven accessory categories	Imaging and accessory manufacturers
19 Oct 2026	Feedback closes on the FDA discussion paper on generative AI enabled devices	Anyone building generative AI into a regulated device
27 Feb 2027	Interim SSCP upload process applies in EUDAMED	Manufacturers of implantable and Class III devices in the EU

The CMS RAPID proposal is the one to read first. If finalised, a device holding FDA Breakthrough designation could receive a proposed national Medicare coverage decision on the same day as its FDA authorisation, compressing a wait that currently runs years into a matter of months. For a company whose American revenue model depends on Medicare coverage, that single change would move the point at which a device starts earning by more than any efficiency programme could. In-vitro diagnostics are excluded from the proposal as drafted, which is itself worth a comment if you make one.

International signals

Saudi Arabia. The SFDA issued its first authorisation under a new innovative-device pathway, giving a route to market that did not previously exist for products without an established comparator in the Kingdom. For a company holding a first-in-class device, a market that previously had no way to assess it now has one.

Abu Dhabi. The Department of Health published new device reporting standards alongside a governance framework for digital health products, part of an emirate-wide digital health programme that also includes a new intelligent surgical network.

China. The NMPA released 46 device standards with implementation staged between 2027 and 2029. Any manufacturer with a China plan should map which of the 46 touch their product now, because the earliest compliance dates arrive in a little over a year and standards work of this kind consumes engineering time that has to be scheduled rather than found.

06 The argument

Every decision in this edition happened after approval.

France graded seven devices against products it already funds and found no improvement in any of them, then refused an eighth from the company that leads its category worldwide. Britain funded a category it had never funded before. A single ventilator fault produced three separate regulatory obligations across three countries in seventeen days. Two FDA authorisations created device classifications that did not exist and wrote the requirements everyone following will be measured against. Hospital technology numbers circulated in procurement conversations on entirely different evidentiary footings.

None of these was a regulator deciding whether a device works. All of them decided whether it sells, whether it stays on the market, what it costs to build, and whether a buyer believes the claim.

There is a shared reason. Approval was the part of this system that got harmonised, standardised, and made predictable, because that is where two decades of European regulatory effort went. Everything downstream of approval stayed national and discretionary, with no mechanism synchronising one country's decision to another's. A company organised around the harmonised problem is organised around the part that no longer decides outcomes.

The work that gets you approved and the work that gets you paid are different work. Only one of them has a published deadline, which is why the other is usually late.

A CE mark

does not tell a health system what it will pay.

An added-benefit grade

does not tell you why, because France publishes the outcome without the reasoning.

A clearance in one market

does not tell you what a safety signal will cost you in the other three.

A published percentage

does not tell you who measured it.

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Which of these decisions is already scheduled against your product?

Every item in this edition sits on someone else's calendar. Establishing which assessments, obligations, and deadlines reach your product is a days-long piece of work against a documented answer, and it is the one thing on this page you can close before the next board meeting.

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