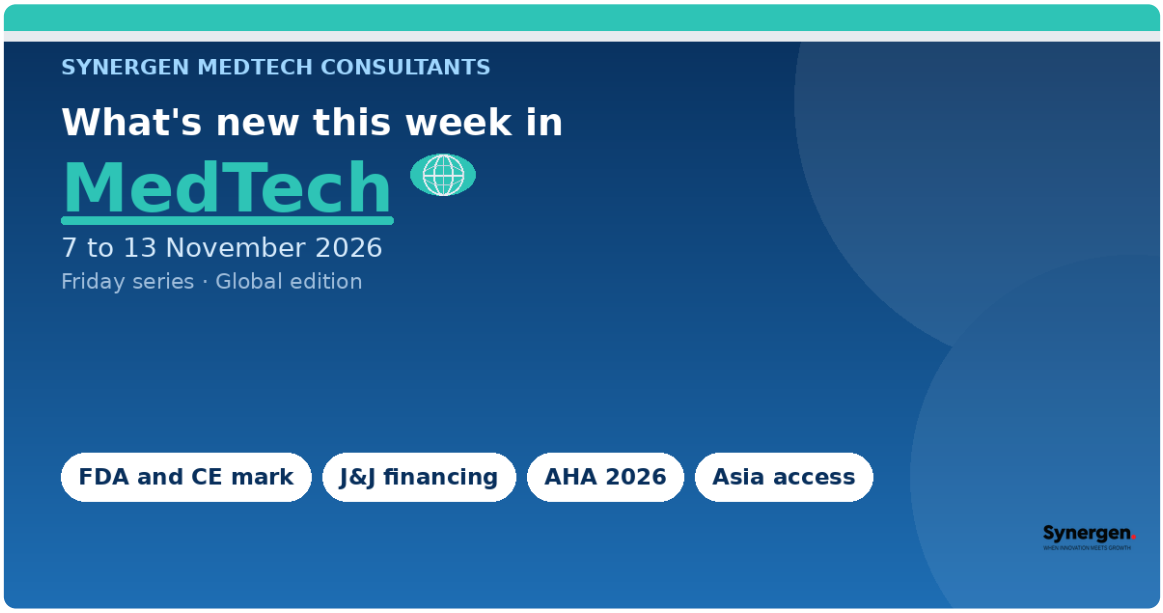


A week shaped by the heart and by the money behind new therapies. Abbott won approval on both sides of the Atlantic for a new defibrillation lead, Johnson & Johnson backed a prostate cancer ablation company, Oura moved from measuring health into delivering care, and AHA 2026 gave us a voice based heart failure study worth reading closely, while a large insulin pump correction and a new FDA guidance on emergency tests reminded us that safety and preparedness never stand still.

1. Abbott wins FDA approval and CE mark for the UltiSynq defibrillation lead

On 10 November Abbott announced FDA approval and CE marking for UltiSynq, a lead built for implantation in the left bundle branch area so that one lead can deliver both conduction system pacing and defibrillation with compatible ICD or CRT-D systems. In the ASCEND CSP trial, implantation succeeded in 202 of 205 patients, 86% achieved left bundle branch pacing or likely pacing, the three month major complication free rate was 97.5%, and defibrillation succeeded in all 120 patients who completed testing. It matters because physicians in the US and Europe implant about 150,000 and 140,000 ICDs a year respectively, and a purpose built lead removes the need for an extra pacing lead in many of those patients.

Source: Cardiac Rhythm News and MedTech Dive

2. Johnson & Johnson leads a financing round in Francis Medical for prostate cancer ablation

On 10 November Francis Medical said Johnson & Johnson Innovation, JJDC, is leading a strategic financing that gives the company enough capital to reach its planned PMA submission for the management of clinically localized prostate cancer. The amount was not disclosed. Its Vanquish water vapor ablation system has had 510(k) clearance for prostate tissue ablation since November 2025, and the VAPOR 2 pivotal study is enrolling 235 patients at 26 US sites, with 91% of the first 110 showing no clinically significant MRI visible cancer in the treated area. It matters because a strategic investor is funding a company through the long PMA road from a tissue ablation tool to a cancer indication.

Source: Francis Medical and MedTech Dive

3. Oura agrees to acquire Counsel Health, moving from wearable insight to physician care

On 10 November Oura announced a definitive agreement to acquire Counsel Health, the AI native, physician supervised care platform it has partnered with since May 2026, so that members can go from a change spotted by the ring to answers and care from a licensed physician inside the Oura App. Counsel physicians can diagnose, treat, order labs and prescribe when appropriate, and the deal is expected to close near the end of this year. Financial terms were not given in the announcement. It matters because a consumer wearable company is buying its way into clinical care, which changes how it will be viewed by regulators, payers and hospital partners.

Source: Oura

4. Cordio Medical reports DETECT-HF voice based heart failure results at AHA 2026

On 9 November Cordio Medical presented DETECT-HF as Late Breaking Science at AHA 2026 in Chicago. In 563 patients at 46 sites, the HearO smartphone voice system detected 52 of 76 first heart failure events, a sensitivity of 68.4%, with the lower confidence bound of 58.0% just below the 60% target, while the unexplained alert rate of 2.65 per patient year met its goal of fewer than three, adherence to daily recordings was 85%, and events were flagged on average 24.1 days before clinical presentation. HearO is not cleared for sale in the US. It matters because it shows both the promise of hardware free remote monitoring and how carefully investors and regulators will read the endpoints.

Source: JACC: Heart Failure and PR Newswire (Cordio Medical)

5. Tandem Diabetes Care issues a correction for more than 80,900 Mobi insulin pumps

MedTech Dive reported on 11 November that Tandem's correction covers more than 80,900 Mobi pumps, mostly in the US, because a false occlusion alarm can suspend insulin delivery until the user acknowledges it. As of 29 October the company had received reports of 230 adverse events needing medical intervention or hospitalization, with no deaths reported, and users have been told they may keep using the pump but must respond to every occlusion alarm and keep a backup way to deliver insulin. It matters because a single mechanical issue at this scale touches patients, clinicians and the payers who fund connected diabetes devices.

Source: MedTech Dive

6. FDA cuts the analytical tests needed for emergency IVDs from 15 to five

On 10 November FDA published final guidance on validating certain in vitro diagnostic tests for emerging pathogens during a Section 564 declared emergency, reducing the recommended analytical studies from 15 to five and supporting pre EUA and EUA submissions. It matters because diagnostic companies can now plan a much leaner validation package before the next outbreak, rather than building one under pressure once it starts.

Source: Federal Register and RAPS

7. Kardi Ai raises CZK 130M Series A to take AI ECG monitoring into Europe and Asia

On 11 November the Czech company Kardi Ai announced a CZK 130 million Series A led by Callisto Health at a post round valuation of CZK 600 million, which it describes as the largest round to date among Czech medtech startups. It already operates in Czechia, Slovakia, Poland, Romania and Bulgaria, received an MD-15 import licence from India's CDSCO in July 2026, holds a UAE Ministry of Health and Prevention registration, and is still working on approval in Singapore as its gateway to Southeast Asia. It matters because it is a clear example of a small European company planning its market access country by country, with registrations in hand before the money arrives.

Source: Unite.AI

8. Baird Medical enters South Korea through a partnership with ALLIS MED

On 12 November Baird Medical (Nasdaq: BDMD) announced that ALLIS MED will act as its Korea License Holder, managing submissions to the Ministry of Food and Drug Safety, and will become the exclusive distributor of its microwave ablation products once certification is received. Thyroid tumor ablation in South Korea is mainly done with radiofrequency today, and Baird says it has entered Argentina, Egypt, Pakistan and Vietnam so far in 2026. It matters because using the local distributor as license holder is a practical way into a regulated Asian market, and it is a model I often discuss with companies planning their first steps in Asia.

Source: GlobeNewswire (Baird Medical)

Gary's take
What I take from this week is that the hard part is rarely the first clearance, it is everything that comes after it, and Francis Medical is a good example, because a 510(k) for a tool got them into the market while the real prize, a cancer indication, still needs a full PMA and a strategic partner patient enough to fund it. Cordio's results are worth reading carefully too, because a study that meets one endpoint and narrowly misses another can still be a strong story, as long as the team explains it honestly to regulators and investors. And having spent more than 30 years working across Asia, I was glad to see the Baird and Kardi Ai stories, because they show what I keep telling founders: choose the right local partner, let them hold the licence where that makes sense, and build your registrations market by market before you scale.

Which of these developments matters most for your company, and is there an area you would like me to cover in more depth next week? You are always welcome to write to me directly, and you can find more of my articles, and book a short introductory call, at synergenmedtech.com.

If you'd like to follow along, you can find us here:

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Sources note: all items were found through a public web scan of the week and each was checked against the linked original source.