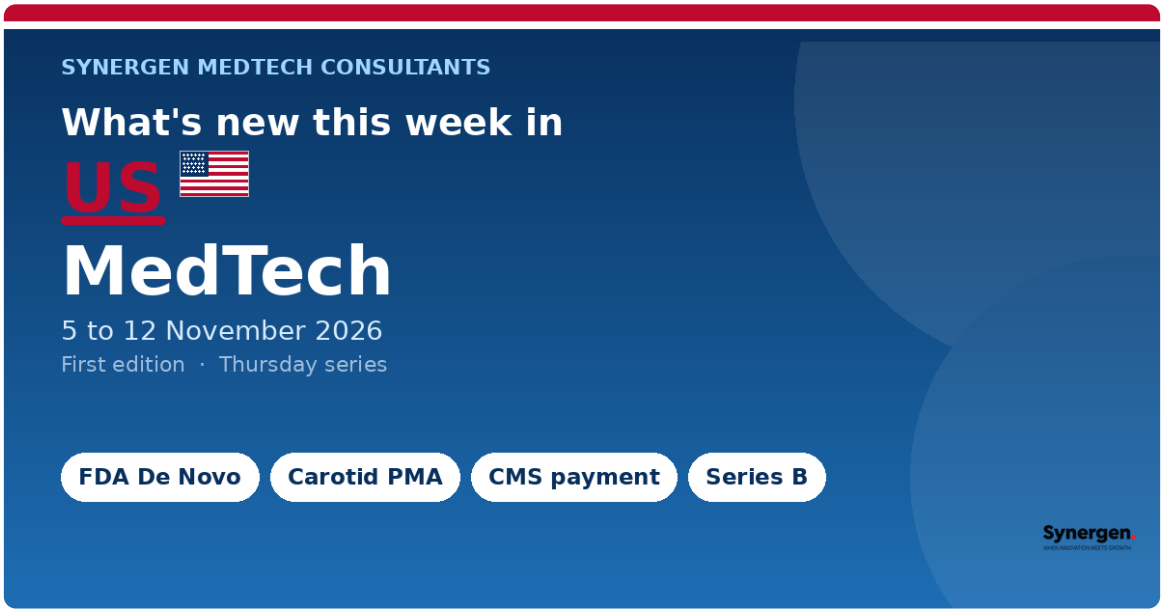


This is the first of a new Thursday series on US MedTech. It was a week in which the FDA both opened doors and closed one: two De Novo authorizations and a carotid PMA, a 510(k) in wound care, a CMS reversal that will pay for a new breast imaging exam, two US financings, and a discussion paper on surgical robots that can work on their own or from a distance.

1. Contego Medical wins FDA PMA for Neuroguard IEP Direct, a new TCAR-IEP approach

On 10 November Raleigh based Contego Medical announced FDA premarket approval of the Neuroguard IEP Direct System and 510(k) clearance of the Neuroguard IEP Embolic Protection System. Used together, they provide dual neuroprotection through flow reversal and an integrated embolic protection filter via direct transcarotid access, which the company describes as a new approach category, TCAR-IEP, for carotid revascularization. In the PERFORMANCE III pivotal study, the 30-day stroke rate was 0% in the intention-to-treat population, with no myocardial infarctions, cranial nerve injuries, neurological deaths or stent thromboses. The primary endpoint, the 30-day rate of major adverse events, was 0.69% in the intention-to-treat population and 0% in the per-protocol population. The earlier Neuroguard IEP 3-in-1 system received FDA PMA approval in October 2024 for transfemoral and transradial carotid stenting and is commercially distributed by Medtronic. It matters because a PMA built on a 0% 30-day stroke rate gives physicians a transcarotid option that adds a filter to flow reversal.

Source: PRWeb (Contego Medical)

2. Virtuoso Surgical receives FDA De Novo authorization for its endoscopic robot

On 10 November Nashville based Virtuoso Surgical announced that the FDA granted De Novo authorization for the Virtuoso Endoscopy System on 30 October 2026. It is the first device in a new FDA classification, electromechanical surgical systems for endoluminal surgical procedures. The system places two needle-sized robotic arms at the tip of a rigid endoscope, giving urologists two-handed dexterity for en bloc resection of bladder lesions through the urethra, so pathologists can receive a tissue sample that includes detrusor muscle. The system received FDA Breakthrough Device designation in September 2025, and Virtuoso plans a focused US launch at leading urology centers in 2027. It matters because a new device class has been created for a small robotic system designed to take a better diagnostic specimen, not only to remove a tumor.

Source: Virtuoso Surgical

3. Theraclion's Sonovein wins FDA De Novo authorization for non-invasive vein treatment

On 5 November French company Theraclion announced that the FDA granted De Novo marketing authorization for Sonovein on 4 November 2026. In the United States, Sonovein is intended for the coagulation of blood vessels in patients with superficial vein reflux in Great Saphenous Vein segments, using high intensity focused ultrasound from outside the body, without an incision or an intravascular catheter. The company says it is the first non-invasive HIFU platform to receive US marketing authorization for this use. Authorization was supported by the VEINRESET pivotal study of 70 patients at four US and European centers (NCT05926830), which met its primary endpoint with a 96.8% GSV occlusion rate at 12 months. No serious or unanticipated adverse events were reported, and only one mild adverse event was observed. A dedicated Category III CPT code has been active since 1 October 2026, which Theraclion describes as an initial step toward coverage and payment. The company has established a US subsidiary, Sonovein Inc., and says it is ready to begin commercial launch. It matters because a European company has opened the US vein market with a truly non-invasive approach, while payment pathways are still being built.

Source: Theraclion

4. FDA declines to approve Novocure's Optune Mya for brain metastases from lung cancer

On 9 November Novocure (Nasdaq: NVCR) said it had received a Not Approvable Letter from the FDA in response to its PMA application for Optune Mya, for the treatment of adult patients with brain metastases from non-small cell lung cancer following stereotactic radiation. The FDA determined that uncertainty around the degree of clinical benefit prevented approval. The agency did not raise concerns related to the safety profile. Novocure plans to meet with the FDA to determine whether there are options that would support approval without additional clinical studies, and cautions that there can be no assurance those discussions will lead to an approval. The company's US headquarters is in Portsmouth, New Hampshire. It matters because even a well known oncology device company can be turned back when the FDA is not convinced of the clinical benefit.

Source: Novocure

5. Luminoah raises $25M Series B, and EnVision Endoscopy closes an $11.5M Series A

On 10 November Charlottesville based Luminoah announced a $25 million Series B financing led by Sandbox Clinical Ventures, with participation from the Blue Venture Fund, GV (Google Ventures), Sands Capital, Texas Medical Center Venture Fund, the CU Healthcare Innovation Fund, the American Gastroenterological Association GI Opportunity Fund, and existing investors. The round includes $20 million in new equity and $5 million in previously issued convertible notes that converted as part of the financing. The money will expand distribution of Luminoah Flow, the company's FDA-cleared enteral feeding system (cleared in April 2026), increase manufacturing capacity, and continue development of Luminoah Intelligence, its clinician-facing data platform. The same day, Waltham based EnVision Endoscopy announced an oversubscribed $11.5 million Series A led by Puma Venture Capital, with participation from UTEC (University of Tokyo Edge Capital), existing investor Olympus Corporation of the Americas, and MassVentures. EnVision received FDA clearance for its SimpleStitch Suturing System in 2025, began a limited US market release in 2026, and has now completed its first 50 patient procedures. It matters because US investors are still funding companies that have already cleared the FDA and are now trying to get the technology into everyday use.

Source: Luminoah and PR Newswire (EnVision Endoscopy)

6. CMS reverses course and will pay for outpatient QTscan breast imaging from 2027

On 9 November QT Imaging Holdings (Nasdaq: QTI) announced that CMS has established separately payable Medicare hospital outpatient payment for medically necessary, physician-ordered diagnostic QTscan examinations, effective 1 January 2027. The decision reverses CMS's earlier proposal to classify QTscan examinations as nonpayable. Under the final 2027 Medicare Hospital Outpatient Prospective Payment System rule, CMS assigned QTscan's dedicated CPT code 1079T to Ambulatory Payment Classification 5522, with status indicator S. The CPT code itself became effective on 1 October 2026. Routine screening of asymptomatic patients is not covered under current Medicare rules, and payment remains subject to medical necessity and documentation requirements. It matters because a clearance without payment often sits on the shelf, and this reversal gives hospitals a real reason to offer the exam.

Source: QT Imaging

7. Bechtel Medical receives 510(k) clearance for Wound VOX, combining negative pressure and topical oxygen

On 10 November Phoenixville, Pennsylvania based Bechtel Medical announced 510(k) clearance from the FDA for Wound VOX. The company describes it as the first 510(k)-cleared system to combine negative pressure wound therapy and topical oxygen therapy on one platform, with three modes: continuous NPWT, intermittent NPWT, and intermittent NPWT with adjunctive topical oxygen. The company notes that topical oxygen therapy has faced reimbursement challenges, and plans a limited commercial release in December 2026. It matters because combining two therapies in one device may make treatment simpler for clinicians, but payment will still decide how widely it is used.

Source: PR Newswire (Bechtel Medical)

8. FDA asks for views on autonomous and remotely operated surgical robots

On 6 November the FDA's Center for Devices and Radiological Health released a discussion paper on evaluating benefit and risk in robotic medical devices with autonomous or remote teleoperation capabilities, including devices for surgery and for positioning or controlling instruments or imaging tools. The paper is for discussion only and does not represent draft or final guidance, and is not intended to propose or implement policy changes. Comments are requested under docket FDA-2026-N-13135 by 5 January 2027. It matters because the agency is inviting a conversation on telesurgery and autonomy before it writes the rules, and companies working in this area should take the chance to speak up.

Source: FDA and American Hospital Association

> **Gary's take**
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> This week I kept coming back to a simple thought: getting through the FDA is only half the job. Contego, Virtuoso and Theraclion all earned important authorizations, and that is genuinely good news for patients. But a device that is cleared and not paid for often waits a long time before it reaches the people who need it. The QTscan story is a reminder of that, because CMS first proposed not to pay and then changed its mind, which is what will actually help hospitals offer the exam from January 2027. Theraclion already has a Category III CPT code, and Bechtel Medical itself notes that topical oxygen still faces reimbursement challenges. The Novocure decision shows the other side, that the FDA will still say no when it is not convinced of the clinical benefit, even for a company that already has products on the market. I would love to hear from people who have lived through this.

Once you have the FDA letter in your hand, what has been the harder part, the regulatory path or getting paid? 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:

Website: synergenmedtech.com
LinkedIn: linkedin.com/company/100981535
YouTube: youtube.com/@synergenmedtech

Sources note: all items were found through a public web scan of about 5 to 12 November 2026 and each was checked against the linked source. Amounts and dates are as reported by the companies or the cited media. NIH SBIR awards announced in this window by Linshom Medical (a $3.5 million Phase 2B grant on 5 November) and Highland Instruments (a Phase IIB award announced on 9 November, with about $1.5 million in current year funding and about $1.4 million in recommended future support, subject to availability of funds and satisfactory progress) were covered in the 3 to 10 November funding and deals edition. Late breaking trial results from TCT were presented on 2 and 3 November, just before this window. No US medtech IPO pricing in this window was confirmed.