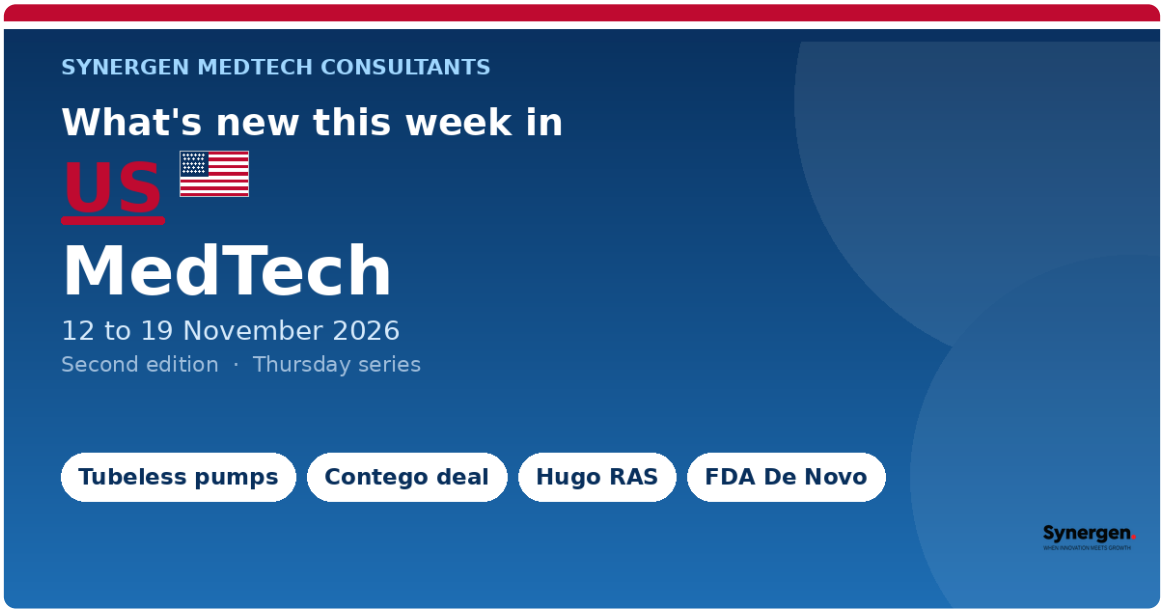


This is the second of our Thursday series on US MedTech. It was a week in which two tubeless insulin pumps were cleared within four days of each other, Medtronic moved to buy Contego after last week's PMA, the Hugo robot was cleared for general surgery, and Roche received a De Novo authorization for automated mass spectrometry in the routine lab.

1. Tandem and MiniMed both receive FDA clearance for tubeless insulin pumps with up to seven days of wear

On 12 November Tandem Diabetes Care (Nasdaq: TNDM), based in San Diego, received 510(k) clearance for a new Tandem Mobi tubeless cartridge and infusion set, which converts the current Tandem Mobi pump into a tubeless device. The company describes it as the world's first and only tubeless automated insulin delivery system with up to seven days of wear. Its 8-K notes that the tubeless infusion set is cleared for up to seven days of wear, while the cartridge is cleared for three days of use. The pump is now cleared for both tubeless and tubed infusion, and it uses Tandem's Control-IQ+ technology. A full US commercial launch is planned for the first half of 2027, with tubeless supplies to be sold exclusively through the pharmacy for customers with pharmacy benefits. On 16 November MiniMed (Nasdaq: MMED), based in Northridge, California, announced FDA clearance of MiniMed Fit, the company's first tubeless insulin pump. MiniMed describes it as the world's first and only tubeless insulin pump with up to seven days of wear and no charging or cartridge changes in that period, with a 300 unit insulin capacity, app control and SmartGuard technology. The company says FDA clearance arrived several months ahead of expectations, and a phased US launch is now expected in spring 2027, earlier than the previously communicated summer 2027 timing. At commercial launch it will offer a choice of two sensors, Simplera Sync with up to seven days of wear and Instinct, made by Abbott, with up to 15 days of wear, and it will also be available through the pharmacy channel. It matters because two established pump companies are now entering the tubeless market in the same season, each with a seven day wear claim, and patients will have more than one new option to compare with today's three day systems.

Source: Tandem Diabetes Care 8-K and MiniMed

2. Medtronic to acquire Contego Medical in a deal valued at $380 million

On 16 November Medtronic (NYSE: MDT) announced its intent to acquire Contego Medical, the Raleigh company whose Neuroguard IEP Direct System received FDA PMA approval last week. The deal is valued at $380 million, with potential payments after the acquisition, and it builds on Medtronic's exclusive US distribution agreement with Contego, first announced in January 2025. The planned acquisition includes Neuroguard IEP Direct, which Medtronic describes as the first and only transcarotid artery revascularization system with integrated embolic protection (TCAR-IEP) in addition to flow reversal, and Contego's Excipio thrombectomy devices. Medtronic expects to complete the transaction in the third quarter of its fiscal year, subject to customary closing conditions. It matters because a distribution partnership has turned into an acquisition, and it follows immediately after a PMA that we covered in last week's roundup.

Source: Medtronic

3. Medtronic's Hugo robot is cleared for general surgery procedures in the US

On 17 November Medtronic announced that the FDA has cleared the Hugo robotic-assisted surgery system for use in general surgery procedures. The 510(k) covers all upper abdominal general surgical procedures, including cholecystectomy, Roux-en-Y gastric bypass, ventral hernia and small bowel resection, as well as the lower abdominal procedures of inguinal hernia and appendectomy. Combined, Medtronic says these procedures account for about 3.5 million surgeries a year in the US, more than half of all soft tissue procedures performed in the country each year. The clearance expands Hugo's US use beyond urology. Globally, the company says Hugo procedure growth is running at more than twice the robotic surgery market and is on track to surpass 50,000 procedures by the end of the Medtronic fiscal year. It matters because general surgery is where most of the soft tissue volume sits, and Hugo can now be used in those procedures in the US, not only in urology.

Source: Medtronic

4. Roche receives FDA De Novo authorization for the cobas pro i 601 mass spectrometry platform

On 16 November Roche announced that the FDA has granted De Novo authorization for the cobas pro i 601 platform with the Ionify Gabapentin assay, part of its cobas Mass Spec solution. The company says the aim is to bring mass spectrometry, which has often been limited to specialized reference laboratories and manual workflows, into routine clinical laboratories through an automated, standardized process. The Gabapentin assay adds therapeutic drug monitoring to a US menu that already includes 25-Hydroxy Vitamin D total and steroid hormone assays such as estradiol and 17-Hydroxyprogesterone. Roche will use an FDA-authorized Predetermined Change Control Plan that covers the addition of up to 22 further Ionify assays on the same platform as the plan's requirements are met. Those additional assays are not yet available. It matters because a De Novo plus a pre-agreed change plan can shorten the path for a whole menu, not only a single test.

Source: Roche

5. InspireMD's CGuard Prime is approved for TCAR, and the first US commercial cases are done

On 12 November Miami based InspireMD (Nasdaq: NSPR) announced FDA approval of a PMA supplement for the CGuard Prime TransCarotid Stent System for use in transcarotid artery revascularization procedures, when used with an embolic protection system specified in the labeling. The company later stated that the FDA approved the device on 9 November. The approval is supported by the CGUARDIANS II pivotal trial, a prospective, multicenter, single-arm US study of 50 patients at 11 sites, using CGuard Prime with the FDA-cleared ENROUTE Transcarotid Neuroprotection System in a high surgical risk population. At 30 days the study reported 100% acute device success, with no deaths, strokes, myocardial infarctions or stent thrombosis, and complete stent patency in evaluable subjects. InspireMD estimates that more than 35,000 TCAR procedures are performed in the US each year, and says the new indication doubles the CGuard Prime platform's total addressable market. On 18 November the company announced the first US commercial TCAR procedures with the system, performed by Dr. Brett Almond in the greater Tampa Bay area, Dr. Gregory T. Clabeaux in Buffalo, New York, and Dr. Bradley R. Grimsley in Dallas, Texas. InspireMD is separately developing SwitchGuard, its own transcarotid neuroprotection system, which is investigational and not available for sale in the United States. It matters because the US carotid market now has another approved TCAR stent option, in the same week that Medtronic moved to buy Contego.

Source: InspireMD (approval) and InspireMD (first commercial cases)

6. Masimo receives 510(k) clearance for smartSedLine brain monitoring during anesthesia

On 18 November Irvine based Masimo, a Danaher company, announced FDA 510(k) clearance for smartSedLine, a next-generation brain function monitoring solution intended to help clinicians assess changes in a patient's response to anesthesia. The company says an enhanced Patient State Index algorithm responds faster during induction and is more stable when EEG power is low. The system is available as a new module and EEG sensor, and the module is plug-and-play with a compatible monitor such as Masimo Root. Masimo says this is its seventh FDA clearance in 2026. It matters because better information on depth of sedation, especially in high risk and older patients, is a practical need in the operating room, not only a new feature on a monitor.

Source: Masimo

7. FDA grants three Breakthrough Device designations, for a urine iNPH test, a spinal graft extender, and a syphilis fingerstick test

On 18 November Haifa based Biostream announced that the FDA granted Breakthrough Device Designation on 12 November for its investigational urine test to aid the diagnosis of idiopathic normal pressure hydrocephalus in patients aged 60 and older, and to help distinguish it from Alzheimer's disease and other neurodegenerative disorders. The test measures a panel of proteins and applies an algorithm to generate a probability score. It is not currently available for sale in the United States, and the company plans a prospective clinical validation study at US academic medical centers during 2027. On 17 November Lund based Moroxite announced a second Breakthrough Device Designation, this time for Xerafuse TOB, a tobramycin-eluting, resorbable bone graft extender intended for sacrolumbar spinal fusion in patients at increased risk of infection. The company's lead product, Xerafuse BMP, received a Breakthrough designation in 2025. A Breakthrough designation is not FDA clearance or approval. Also on 17 November Halifax based MedMira (TSXV: MIR) announced Breakthrough Device Designation for its Multiplo Complete Syphilis (TP/nTP) Antibody Test, an instrument-free fingerstick test that simultaneously detects treponemal and non-treponemal antibodies from whole blood. MedMira also said that, following the designation, FDA's Total Product Life Cycle Advisory Program team invited the company to apply for enrollment in its TAP Pilot. It matters because Breakthrough status can speed the conversation with the FDA, but it is still only a starting point, and none of these three tests or devices is cleared for US sale on the back of this week's news.

Source: PR Newswire (Biostream) and Moroxite and MedMira

> **Gary's take**
> This week I kept coming back to how quickly a market can fill up once the first clearance arrives. On 12 November Tandem said it had the world's first and only tubeless automated insulin delivery system with up to seven days of wear. Four days later MiniMed said much the same about MiniMed Fit, with a 300 unit reservoir and no cartridge change for up to seven days. Both plan to launch in 2027, and both will be going after today's tubeless market as well as each other. The fine print matters here, because Tandem's cartridge is cleared for three days even though the infusion set can stay on for seven. In carotid care the story continued from last week: Medtronic is now buying Contego, the company whose Neuroguard IEP Direct system we wrote about after its PMA, and InspireMD has already started its first commercial TCAR cases with CGuard Prime. That is what a competitive US market looks like, and it is generally good for physicians and patients, as long as we keep reading the labels and the payment rules with the same care we give to the press releases.

When two clearances land in the same week and both claim to be first, what do you look at first, the wear time, the clinical data, or how the device will actually be paid for and supplied? 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.

Sources note: all items were found through a public web scan of about 12 to 19 November 2026 and each was checked against the linked source. Amounts and dates are as reported by the companies or the cited media. The Medtronic agreement to acquire Contego Medical, the vVARDIS IPO and the Remedy Robotics Series B were covered in the 10 to 17 November funding and deals edition; Contego is included here because it follows last week's PMA and is central to this week's US carotid story. No new CMS payment decision in this window was added, and no additional US medtech IPO pricing was confirmed beyond the vVARDIS offering already covered on Tuesday.

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