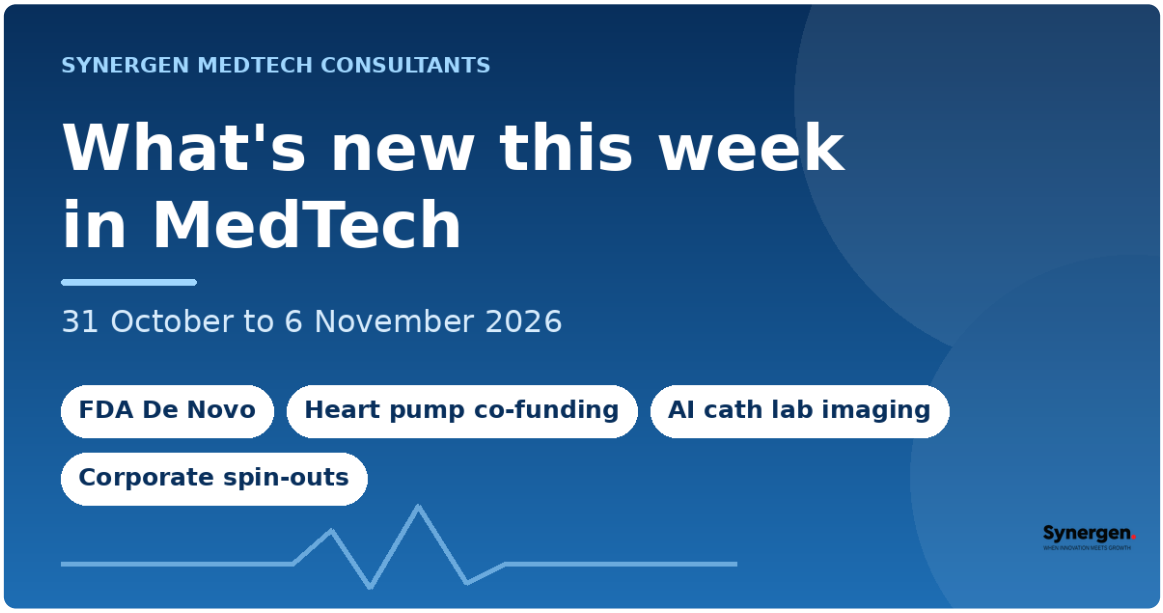


A busy week for clearances and capital: FDA opened a new non invasive vein care category, Boston Scientific locked in a large heart pump co funding deal, AI imaging raised a major Series B, and Siemens Healthineers set out a path to rename and carve out diagnostics, while real world hypertension data and a long running recall settlement both moved the needle for market access.

1. Theraclion wins FDA De Novo for Sonovein, a non invasive HIFU treatment for varicose veins

On 4 November Theraclion announced FDA De Novo marketing authorization for Sonovein for coagulation of blood vessels in patients with superficial venous reflux in Great Saphenous Vein segments, describing it as the first non invasive high intensity focused ultrasound platform authorized in the United States for this use. The filing was supported by the VEINRESET pivotal study in 70 patients, which reported 96.8% GSV occlusion at 12 months as the primary endpoint, and a Category III CPT code for non invasive HIFU vein procedures has been active since 1 October 2026. It matters because it opens the large US varicose vein market to an incision free modality and creates a new device classification through the De Novo route.

Source: Business Wire (Theraclion)

2. Boston Scientific and Blackstone Life Sciences agree up to $455M to co fund the Vitalyst heart pump

On 2 November Blackstone Life Sciences said it will provide up to $455 million to co fund development of Boston Scientific's VITALYST Temporary Percutaneous Transvalvular Circulatory Support System for acute myocardial infarction cardiogenic shock, the first Blackstone Life Sciences co funding of a Boston Scientific product. Blackstone may receive regulatory and commercial milestones of up to about 2.5 times capital plus royalties, and Boston Scientific has pointed to commercial timing around 2030. It matters because a high mortality indication is getting one of the largest external co funding packages in medtech this year, which is a model more device companies will watch closely.

Source: Blackstone and MedTech Dive

3. Laza Medical raises up to $160M Series B led by GE HealthCare for AI robotic cath lab imaging

Announced on 4 November, the Shifamed portfolio company closed a Series B structured financing of up to $160 million led by GE HealthCare, with Unorthodox Ventures, PA MedTech and AMED also participating, to advance its AI powered robotic imaging system for the cath lab. The system is not approved for commercial sale anywhere. It matters because it pairs a large imaging OEM with an AI robotics startup at scale, and it was one of the week's biggest device financings.

Source: PR Newswire (Laza Medical)

4. FX Shoulder Solutions gets FDA 510(k) for the first stemless reverse shoulder system in the US

On 5 November FX Shoulder Solutions announced FDA 510(k) clearance for Easytech Reversed, which it describes as the first and only FDA cleared stemless reverse shoulder arthroplasty system in the United States. Clearance follows an IDE started in 2018 across 7 sites and 90 patients, with follow up completed in 2023, and the design uses peripheral proximal humeral fixation without a conventional diaphyseal stem. It matters because it creates a new US option category in reverse shoulder replacement after a long clinical path.

Source: PR Newswire (FX Shoulder Solutions)

5. Medtronic Symplicity Spyral shows large real world blood pressure drops and gains a labeling update

At TCT 2026 on 3 November, Medtronic reported six month results from the US primary cohort of SPYRAL AFFIRM, an FDA designed post approval study: office systolic blood pressure fell 18.2 mmHg, home 9.4 mmHg and 24 hour ambulatory 9.7 mmHg, with medication count unchanged at 3.6 and a composite safety rate of 2.1%. The same day FDA approved a US labeling update that adds clinical evidence for isolated systolic hypertension, chronic kidney disease up to stage 3b (eGFR of 30 or above) and type 2 diabetes, while the indication for use itself is unchanged. It matters because real world evidence and broader labeled evidence help hospitals decide who to treat, even when the formal indication stays the same.

Source: Medtronic News

6. Philips books EUR 288M for a DOJ agreement in principle over the Respironics recall

On 3 November, with its Q3 results, Philips said Respironics reached an agreement in principle with the US Department of Justice to resolve criminal and civil investigations tied to the sleep and respiratory device recall, and recorded a provision of EUR 288 million (about $322 million as reported by trade press). Settlement is still subject to final documents, with payment expected in Q1 2027, and a separate US state attorneys general investigation remains open. It matters because one of the industry's defining recalls is moving toward a criminal and civil resolution, which clears a large overhang even as state level work continues.

Source: Philips SEC Form 6-K / Q3 materials and Fierce Biotech

7. Evident Vascular wins FDA 510(k) for an AI powered peripheral IVUS platform

On 4 November Evident Vascular announced FDA 510(k) clearance of the Evident Vascular Guidance System and Evident peripheral imaging catheters for ultrasound examination of intravascular pathology during peripheral vascular interventions. The platform emphasises high fidelity imaging, an AI workstation, flushless plug and play catheters and voice control, with NVIDIA accelerated processing. The company still notes that the system and catheters are not available for sale in the United States. It matters because peripheral IVUS is a workflow critical imaging niche, and an AI forward entrant raises the bar for competitors already in the cath lab.

Source: Evident Vascular

8. Siemens Healthineers to become Healthineers and carve out diagnostics as Olyrian

On 5 November Siemens Healthineers said it will become Healthineers after the planned 2027 deconsolidation and spin off from Siemens, with shareholder votes expected in February 2027. Separately, its in vitro diagnostics business begins a carve out under the brand Olyrian Diagnostics, aiming to stand alone by mid 2028 while remaining part of Healthineers during the transition. It matters because one of the largest imaging and diagnostics groups is reshaping its name and structure, which will affect partners, competitors and talent across 117 countries and beyond.

Source: Siemens press and Siemens Healthineers (Olyrian)

Gary's take
What stands out for me this week is how many companies are using De Novo and 510(k) not just to get a product cleared, but to open an entirely new category, as Theraclion and FX Shoulder both did, and I would encourage any founder with a real unmet need that does not fit a predicate to look at De Novo early rather than forcing a 510(k) that does not fit. The Blackstone and Boston Scientific co funding model is also worth studying if you are raising for a capital heavy pivotal programme, because sharing late stage cost with a deep pocketed partner can protect your balance sheet without giving away the whole franchise. On the EU and large corporate side, name and structure changes like Healthineers do not change your CE plan overnight, so keep building on today's rules and treat the spin outs as a signal of where the big groups are placing their bets.

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.

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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.