

Avania

MedTech's Trusted Champion

MedTech Industry Pulse

March 2026 Update



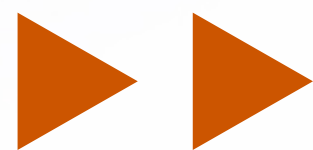
Executive Summary

- ▶ **358 MedTech Clinical Trial starts in Q1 '26 – 29% increase vs Q1 '25**
 - YTD Cardiovascular, Neurology, Ophthalmology & Oncology represent 48% of all study starts
- ▶ **Half of all Q1 '26 study starts are exploratory / pilot studies**
 - Less than 5% of all Q1 '26 starts are Pivotal Trials
- ▶ **LSI & J.P. Morgan are reporting \$2.4B & \$2.5B of Venture Capital deals in Q1 '25**
 - LSI reported 78 deals @ \$30.77M per deal; J.P. Morgan reported 79 deals @ \$31.65M per deal
- ▶ **WHOOOP raised \$575M at a \$10.1B valuation in a Series G funding round led by Collaborative Fund**
 - Neuromodulation gaining steam with Cognito Therapeutics, Neurolief & Aneuvo raises
- ▶ **4 PMA Approvals granted to LivaNova, JenaValve, Boston Scientific & Perimeter Medical Imaging AI**
- ▶ **2 DeNovo Approvals granted to TytoCare, Ltd & LifeVac, LLC**
- ▶ **744 510(k)s filed in Q1 '26 – flat to Q1 '25 (also with 744)**

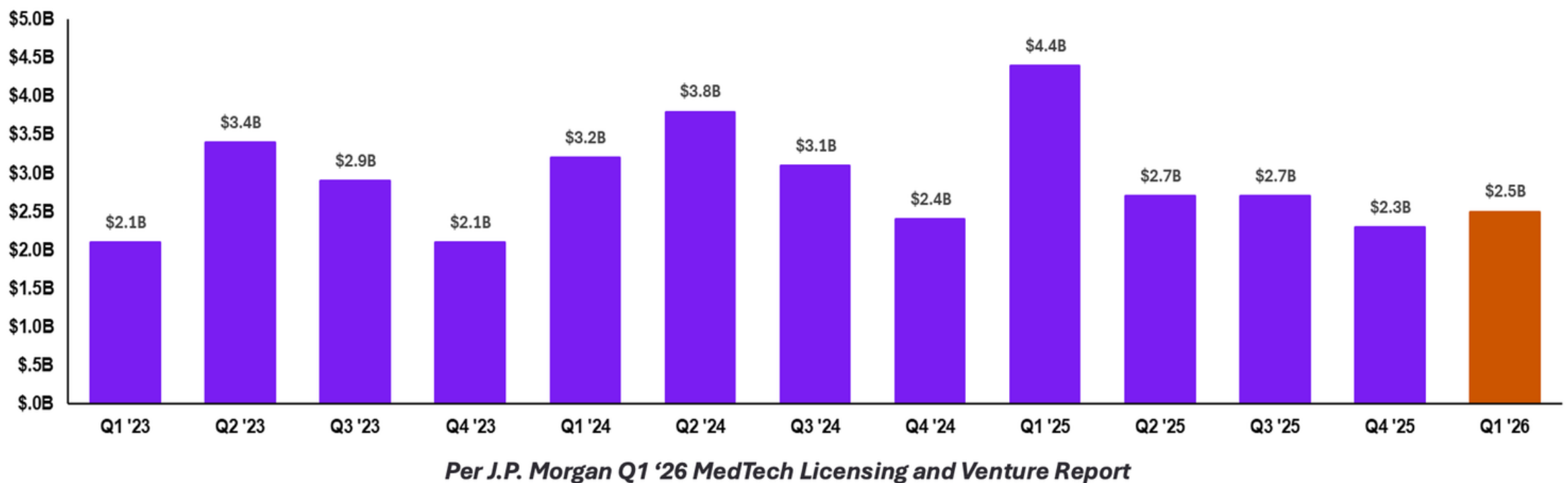


MedTech Companies With Funding Reported in March 2026

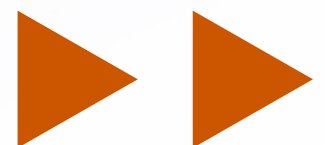
Company	Country	Funding Stage	Amount	Focus
WHOOOP	USA	Series G	\$575M	Wearable health/fitness tracker
Cognito Therapeutics	USA	Series C	\$105M	Neuromodulation
Vitestro	Netherlands	Series B	\$70M	Autonomous Robotic Phlebotomy Device
Lenoss Medical	USA	Bridge Round	\$60M	Cementless biologic implant for spinal fracture
Thrombolex	USA	Series A	\$50M	Interventional devices
Endogenex	USA	Series C	\$50M	Endoscopic pulsed electric field solution to treat Type 2 Diabetes
Hyperfine	USA	Debt Financing	\$40M	Portable brain MRI system
Neurolief	USA	Growth	~\$40M	Neurostimulation
ProSomnus Sleep Tech	USA	Series B	\$38.0M	Oral device
Nuvaira	USA	-	\$35.8M	Respiratory therapeutics
XCath	USA	Series C	\$30M	Endovascular robotics and steerable guidewires
Monteris Medical	USA	Series E	\$28M	Precision-guided laser therapy for treatment of brain tumors & epileptic foci
Echopoint Medical	UK	Other	\$25M	Optical fiber ultrasound sensors to improve cardiovascular disease
Aneuvo	USA	Series C	\$22M	Neuromodulation
Minnesota Medical Tech	USA	Series A	\$20.6M	Medical device innovation
Petal Surgical	USA	Bridge Round	\$15M	Incisionless surgery platform
Abram Scientific	USA	Series A	\$11.75M	Coagulation device
HEPTA Medical	France	Series A	\$11.55M	Minimally invasive non-surgical treatment modality for early lung cancer
Bioliberty	USA/UK	Series A	\$10.2M	Assistive device and platform for hand weakness
Sub-Q Bionics	USA	Seed	~\$5-10M	Implantable
Noah Labs	USA/Germany	Grant	\$3.47M	AI-based remote patient monitoring for cardiovascular health



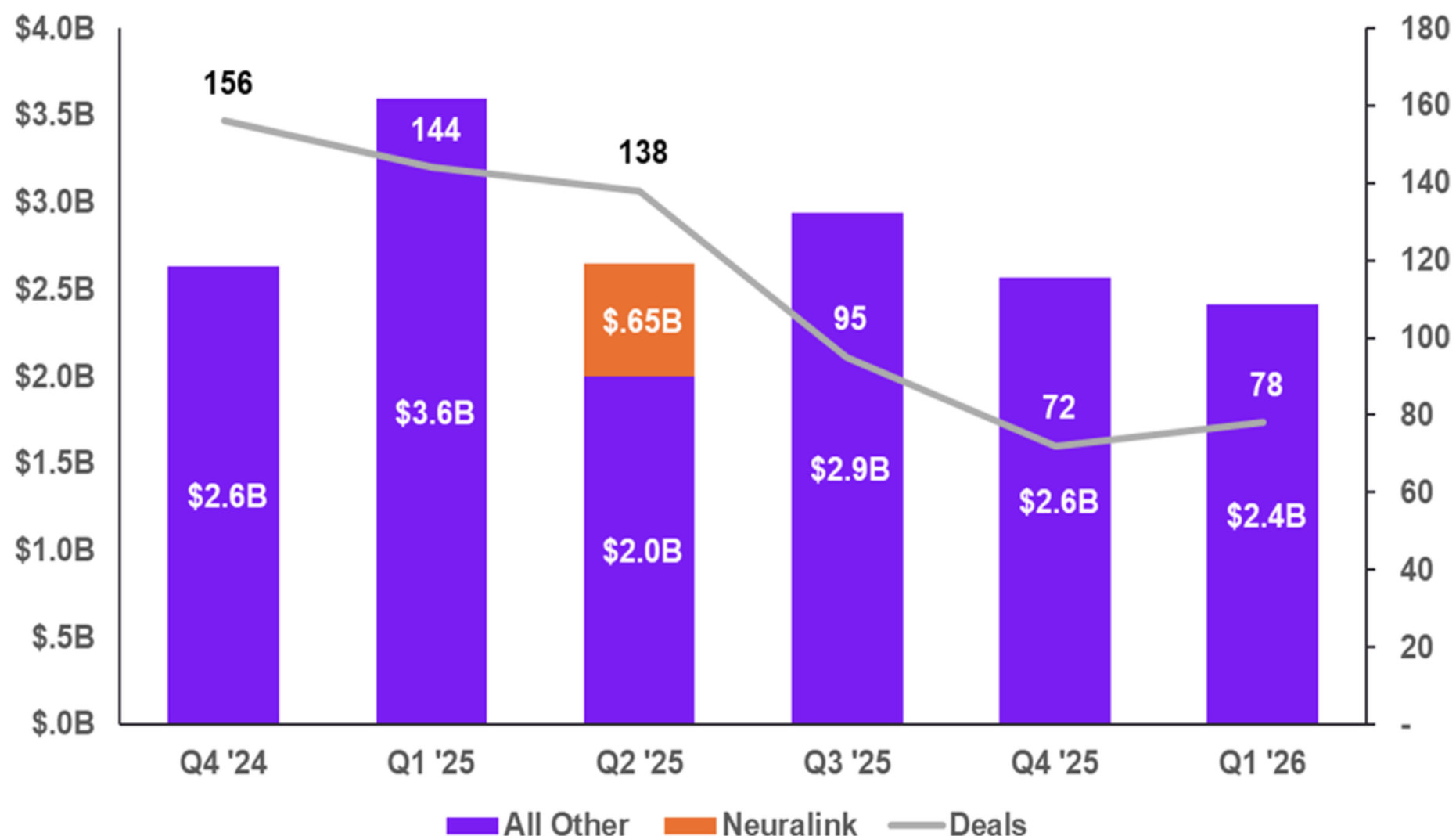
JP Morgan MedTech Venture Capital Funding Trend



- ▶ Q1 '26 funding up \$0.2B vs Q4 '25, down \$1.9B vs 'Q1 2025
- ▶ 79 deals in Q1 '26 with an average value of \$31.65M



LSI MedTech Funding Trend



- ▶ From Q4 '24 to Q2 '25: \$8.85B / 438 deals, From Q3 '25 to Q1 '26: \$7.9B / 245 deals (44% drop in companies receiving funding)
- ▶ After normalizing for Neuralink deal in Q2 '25, overall funding in the above periods is similar: \$8.25B vs \$7.9M
- ▶ Average deal size has jumped from \$18.8M (Q4 '24 to Q2 '25) to \$32.3M (Q3 '25 to Q1 '26)
- ▶ Q1 '26 vs Q1 '25 overall funding is down 33% (\$2.4B vs \$3.6B)



Q1 '26 MedTech Planned / Completed M&A

Buyer	Target	Approx. Value / Focus
Smith & Nephew	Integrity Orthopaedics	~\$450M, Rotator cuff repair devices
Boston Scientific	Valencia Technologies	Neuromodulation tech
BioStem Technologies	BioTissue Surgical & Wound Care	~\$15M + milestones, Surgical & wound care products
W. L. Gore & Associates	Conformal Medical	Structural heart implants
Haemonetics	Vivasure Medical	~€185M, Vascular closure devices
Resonetics	Resolution Medical	Expands structural heart and neuromodulation design & mfg
Boston Scientific	Penumbra	~\$14.5 B, vascular/neuro devices
Alkem MedTech	Occlutech	€99.4M, structural heart implants
BD & Waters	n/a (combination)	Diagnostics & biosciences
Medtronic	CathWorks	~ \$585 M, cardiac devices
Precision IO Group/Quantum Surgical	NeuWave Medical	Robotics + tumor ablation tech
Zavation	ChoiceSpine	Spine devices
GCM	Kettmann Machining	Precision medtech mfg
Maxx Orthopedics	TracPatch	Remote ortho monitoring
Danaher	Masimo	\$9.9B, Patient monitoring
Guardant Health	MetaSight	\$59M, Diagnostics
Tactile Medical	LymphaTech	\$6.8M + milestones, Lymphedema / Digital + device
Abbott	Exact Sciences	\$21B, Cancer screening
Medtronic	Scientia Vascular	\$550M, Neurovascular
Merit Medical	View Point Medical	\$140M, Tumor tissue localization devices
Embecta	Owen Mumford	\$201M, Drug delivery systems

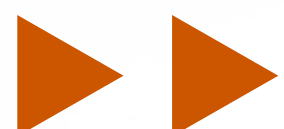


Medtech Regulatory & Market Access - March 2026

Regulators ease innovation pathways while tightening compliance — the MedTech paradox of Q2.



1. FDA workforce reductions per HHS announcement March 27, 2026; Office of Digital Transformation 40% reduction per FedScoop reporting: <https://www.fiercehealthcare.com/regulatory/rfk-jc-prepares-10000-job-cuts-across-hhs-new-wave-worker-reductions> & <https://fedscoop.com/fda-tech-officials-complied-with-doges-requests-for-data-the-staff-reductions-still-came>
2. Penalty per Therapeutic Goods (Medical Devices) Regulations 2002, as amended; effective March 21, 2026. Australian Therapeutic Goods Administration (TGA) on the regulations: <https://www.tga.gov.au/resources/legislation/therapeutic-goods-medical-devices-regulations-2002>



1Q 2026

Cybersecurity Transformation

Agentic AI cybersecurity changes the game, how are MedTechs responding?



On April 7th, new AI model “Mythos” (Anthropic) was released that shifts the cybersecurity landscape. New paradigm-shifting agentic AI tools catalyze investment in MedTech cybersecurity.



Cybersecurity Just Changed for Every Connected Device

The trifecta signaling that FDA 524B is no longer complete for the attacker.



Fallout from Stryker Cyber Attack (Mar 11) — Cloud is the new attack surface

On March 11th, Iran-linked Handala group weaponized Microsoft Intune to wipe ~80,000 devices across 79 countries with no malware deployed, including downtime for Stryker's Lifenet electrocardiogram system. Cloud management is now an attack surface.



Mythos + Glasswing (Apr 7) — Powerful AI agents launch for cybersecurity

Anthropic launched new *Mythos Preview* AI model (not available to public) and \$100M cybersecurity consortium (AWS, Google, Microsoft, CrowdStrike, Linux Foundation, etc.) disclosed 1000s of zero-days. 99% remain unpatched.



For Less than \$50, Cutting-Edge AI found 27-year old critical vulnerabilities

Mythos autonomously found and exploited a 27-year-old OpenBSD bug and a 17-year-old FreeBSD remote-root flaw.¹ Every connected medical device on the market today was cleared without defenses against this class of attacker.

Standards bodies and regulators prioritize cybersecurity in 2026:



- ▶ AAMI CR515:2025 recognized by FDA Feb 19 as the first AI/ML device cybersecurity consensus standard



- ▶ CISA + HSCC previewing 2026 healthcare AI cybersecurity guidance; secure-by-design expectations extending to agentic systems

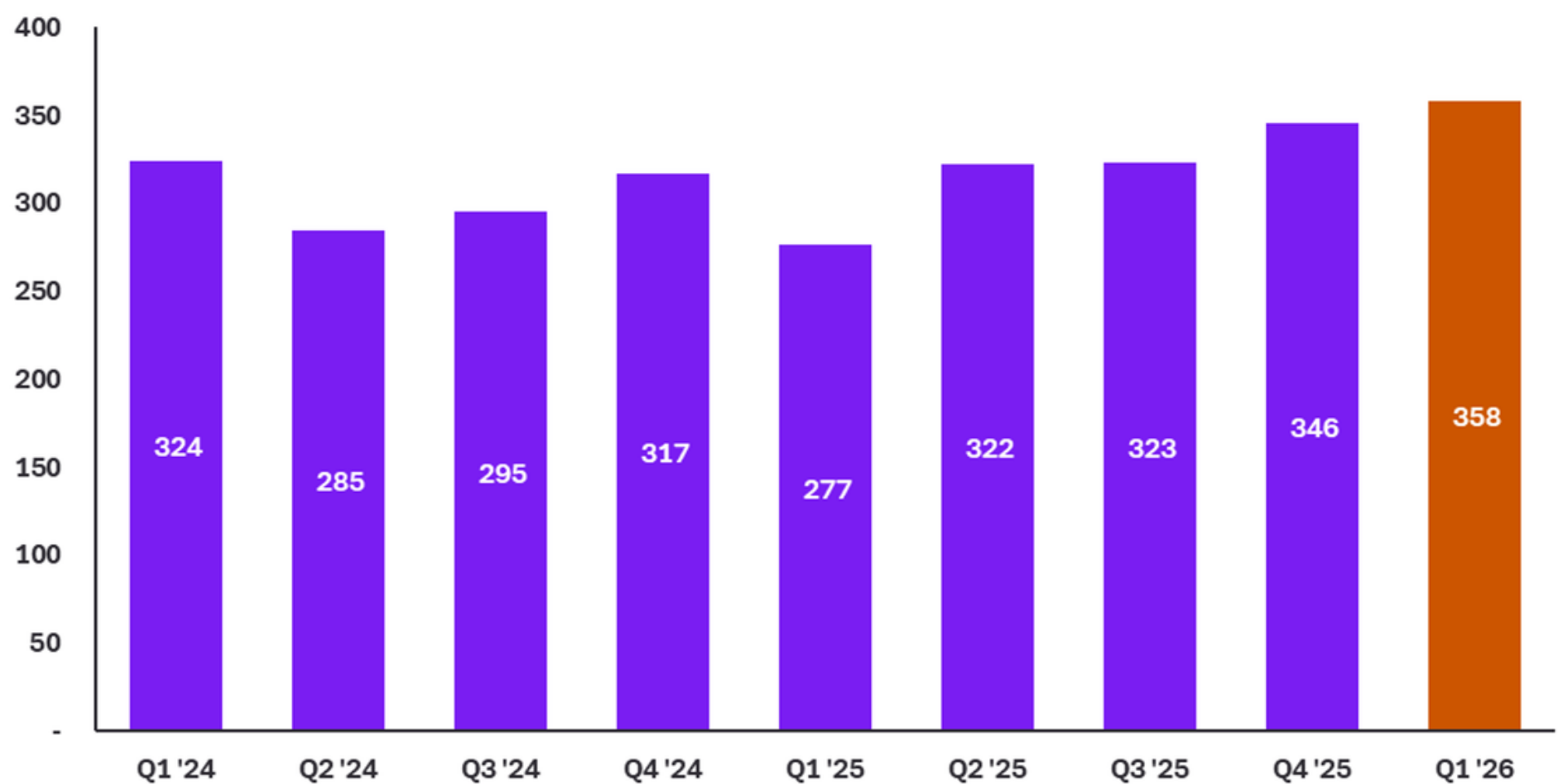


- ▶ NIST PQC transition (FIPS 203/204/205) and NIS2 enforcement in EU compounding compliance for connected medical devices



¹ 17-year-old FreeBSD RCE (CVE-2026-4747) granting remote root via NFS, plus a 27-year-old OpenBSD crash bug
<https://red.anthropic.com/2026/mythos-preview>, <https://simonwillison.net/2026/Apr/7/project-glasswing>

Quarterly Device Clinical Trial Starts Trend

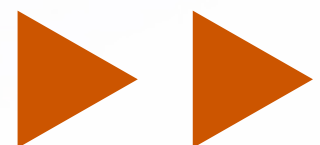


29% Year over Year growth vs Q1 '25

▶ **Source:** ClinicalTrials.gov

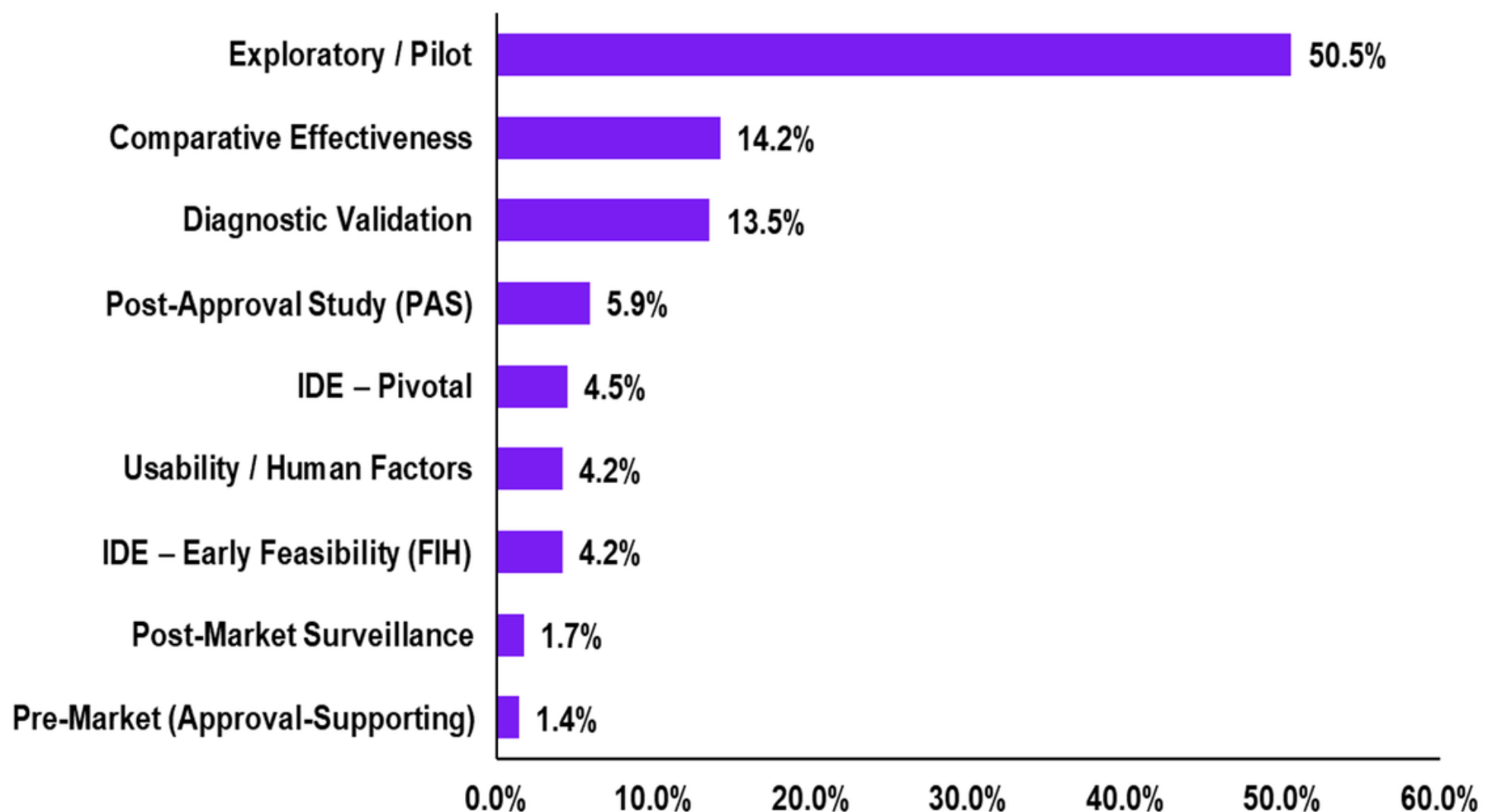
▶ **Search parameters:**

- Start dates between 1/1/26 – 3/31/26
- Device indication
- Interventional studies
- Industry funded

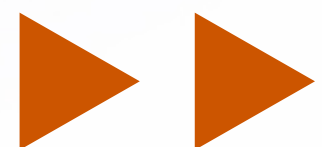


March '26 YTD

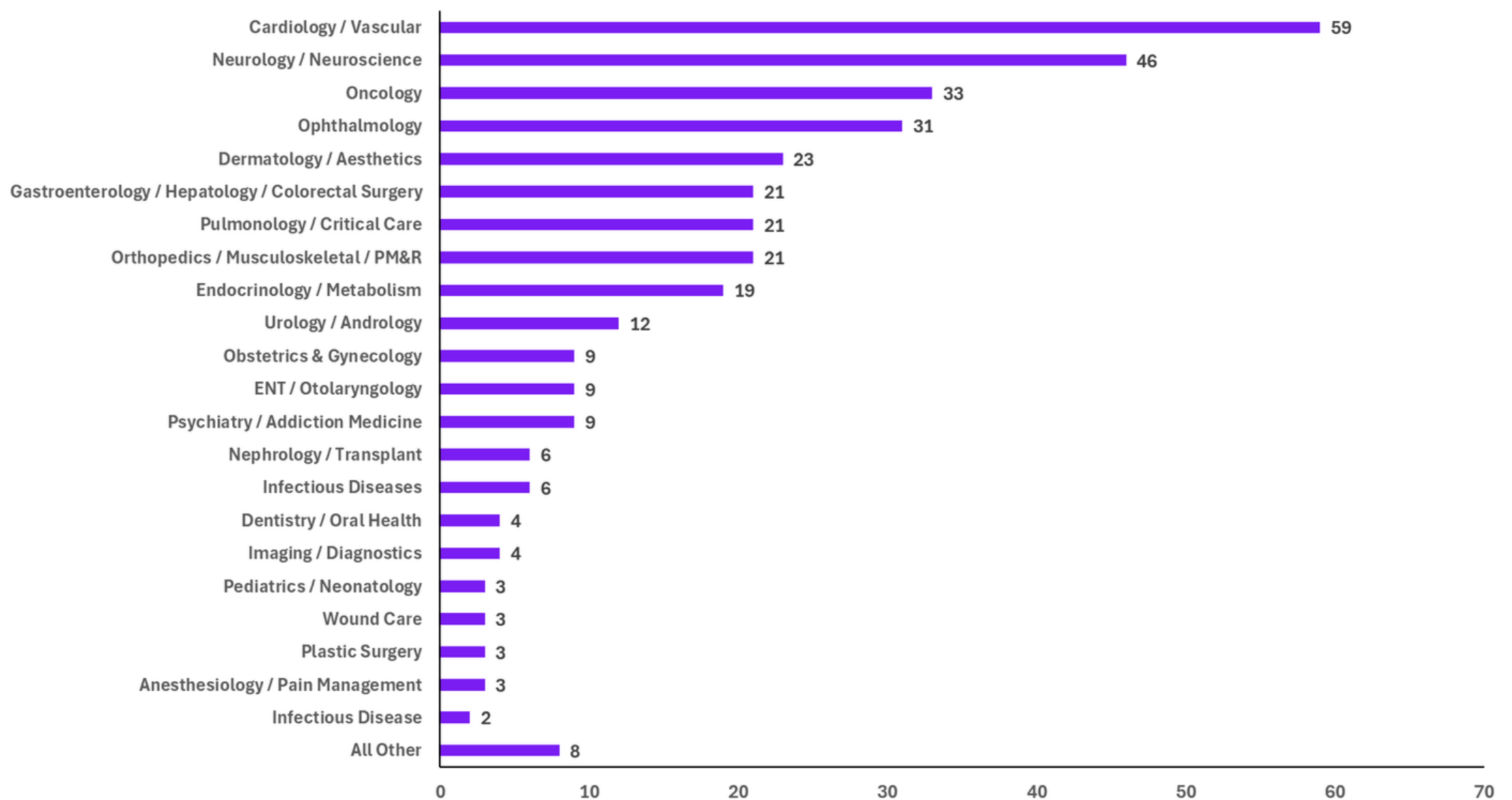
Study Starts by Study Type



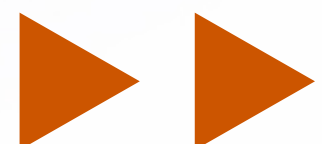
- ▶ **Source:** ClinicalTrials.gov
- ▶ **CoPilot provided study types**
- ▶ **Search parameters:**
 - Start dates between 1/1/26 – 3/31/26
 - Device indication
 - Interventional studies
 - Industry funded



March '26 YTD Device Clinical Trial Starts by Therapeutic Area



- ▶ Cardiovascular, Neurology, Ophthalmology & Oncology
48% of all study starts
- ▶ Therapeutic designation per Co-Pilot
- ▶ Trial data per ClinicalTrials.gov: Interventional, industry funded, device indication



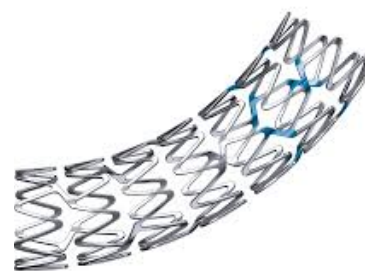
March 2026 PMA Approvals



- **Sponsor:** LivaNova, USA
- **Device:** aura6000™ system
- The device is indicated for the reduction of apneas, hypopneas, or both in adult patients with moderate to severe obstructive sleep apnea (OSA).



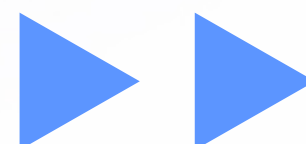
- **Sponsor:** JenaValve Technology, Inc
- **Device:** Trilogy Transcatheter Heart Valve System
- Indicated for the treatment of symptomatic, severe native tricuspid aortic valve in patients who are judged by a Heart Team, including a cardiac surgeon, to be at high or greater risk for surgical aortic valve replacement.



- **Sponsor:** Boston Scientific Corp
- **Device:** Rebel Platinum Chromium Coronary Stent System Monorail and Over the Wire
- This device is indicated for improving coronary luminal diameter in patients with de novo lesions ≤ 28 mm in length in native coronary arteries with a reference vessel diameter (RVD) of ≥ 2.25 to ≥ 4.50 mm



- **Sponsor:** Perimeter Medical Imaging AI, Inc.
- **Device:** Claire™ OCT System
- Intended for use in conjunction with other standard methods for evaluation of the margins of excised lumpectomy tissue during surgical procedures in patients with a biopsy-confirmed diagnosis of breast cancer.



March 2026 De Novo Approvals



Tyto Insights for Eardrum Bulging Detection

- **Sponsor:** Tyto Care, Ltd
- Review Advisory Committee: Ear Nose & Throat
- An over-the-counter web-based AI-enabled software analytics device intended to automatically detect the bulging of the eardrum in Otoscopic video recordings acquired by the compatible electronic otoscope, as identified in the product labeling, in patients aged 6 months and older.

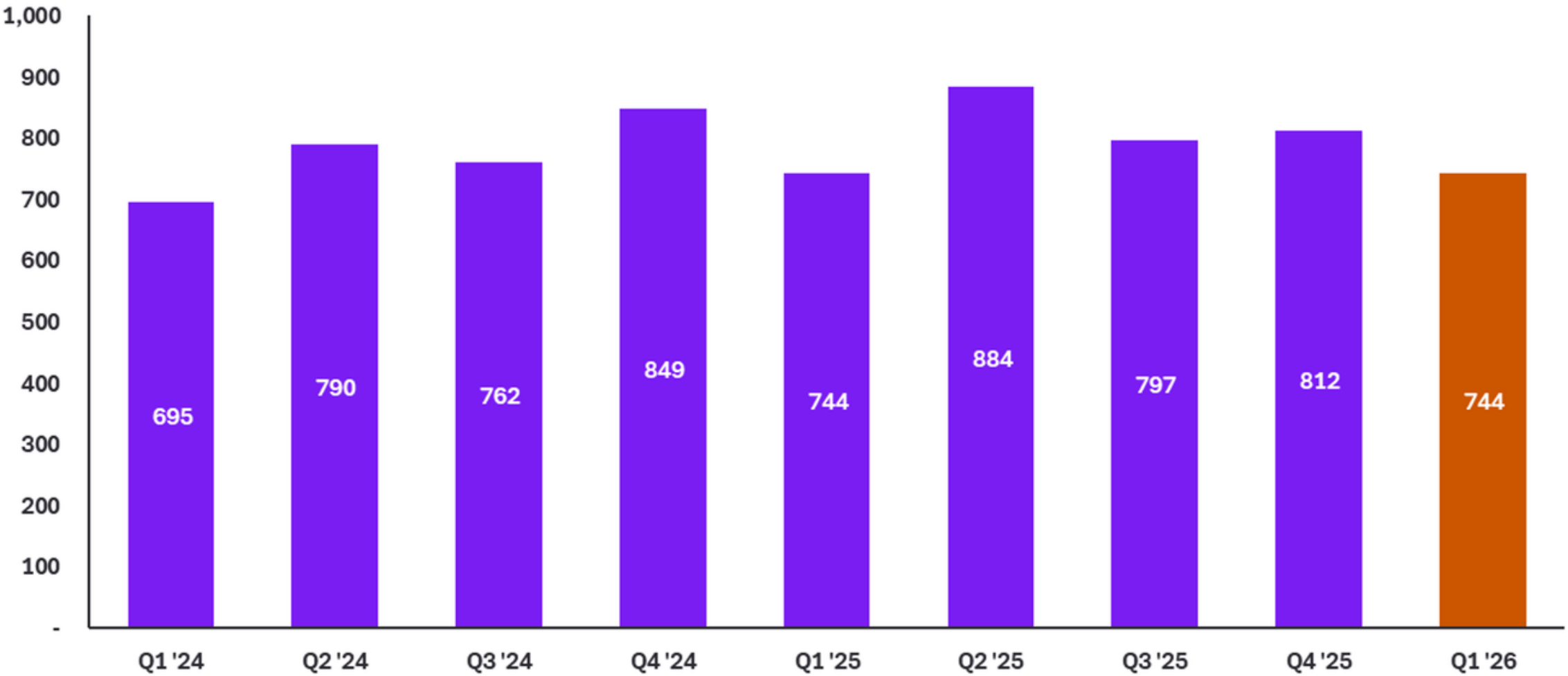


LifeVac

- **Sponsor:** LifeVac, LLC
- Review Advisory Committee: Ear Nose & Throat
- A non-powered, non-invasive, single-use-only airway clearance device intended to resolve choking in a victim with a complete airway obstruction when a current choking protocol has been followed without success.



510(k) Monthly Trend – Continues Trend of Low Q1s



▶ Source: www.fda.gov



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Your MedTech

Innovation?

Partner with Avania And experience the difference of the MedTech-only CRO: trusted expertise, collaborative engagement, and proven results.

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