MedTech Industry Pulse

May 2026

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April ‘26 Summary

- **FDA-CMS launch RAPID Coverage Pathway**
- **Martin Makary resigned as head of FDA on May 12**
- **100 MedTech Clinical Trial starts in April – roughly flat to March (103)**
  - YTD Cardiovascular represents 24% of all study starts
  - Data now only includes Industry funded trials
- **Sidewinder Therapeutics & Gardner Health raised $250M+**
- **Alamar Biosciences raised $191.3M via IPO**
- **3 key acquisition announcements:**
  - American Industrial Partners acquired Avanos
  - Stryker acquired Amplitude Vascular Systems
  - Stereotaxis acquired Robocath
- **PMA Approval: NEXUS Aortic Arch Stent Graft System**
- **De Novo Approvals:**
  - XPlantR Xlant Tool
  - Neuropacs
  - Aurie System
- **HDE Approval: River Stent System**

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April ‘26 Funding Successes

Company	Stage	Country	Subsector	Funding (USD)
Sidewinder Therapeutics	Series B	USA	Drug-device therapeutics	$137M
Garner Health	Series B/C	USA/UK	Care optimization platform	$118M
AcuityMD	Series C	USA	Medtech AI / commercial intelligence	$80M
Route 92 Medical	Growth	USA	Stroke intervention devices	$50M
Anterior	Series A/B	USA	AI workflow automation	$40M
Aneuvo	Series C	USA	Neurostimulation devices	$22M
Sonire Therapeutics	Series A	Japan	High-intensity focused ultrasound (HIFU) for	$18M
Jimini Health	Series A	USA	Digital health / AI therapy	$17M
Plaquetec		UK	Cardiovascular disease database	$5M
Cerca Magnetics	Series A	UK	Wearable brain imaging using quantum sens	$4.7M
auryx	Pre-seed	UK	Turning consumer earbuds into continuous	$2M
Theta Neuro	Pre-seed	USA	Wearable EEG patch for seizure prediction	$2M
Andromeda Surgical	Seed	USA	Surgical devices	≈ $1.0M
Lumius	Seed	USA	Medical devices / digital health	$0.5M

April ‘26 Initial Public Offerings (IPO)

ALAMAR BIOSCIENCES

$191.3M Raised

Founded in 2018, Alamar develops instruments to detect low-level protein biomarkers in blood, enabling disease research and diagnostics.

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Announced M&A

AMERICAN INDUSTRIAL PARTNERS

$1.27B Private Equity Buyout

AVANOS*

stryker

Value not disclosed

AVS

PULSE INTRAVASCULAR LITHOTRIPSY

STEREOTAXIS

Pioneering Endovascular Robotics

≈45M Acquisition

Robocath

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INSIGHTS
REGULATORY & MARKET ACCESS

Regulatory & Market Access April ‘26

Trends top Watch in the Market Access and Regulatory Landscapes to position for Q2 ‘26

Market Access

Changes to coverage for breakthrough devices

- **FDA-CMS launch RAPID Coverage Pathway (Apr 23),** faster Medicare coverage decisions for Breakthrough Devices via FDA-CMS alignment.
- **CMS proposes to repeal the TPT/NTAP alternative pathway for breakthrough devices (Apr 10),** substantial clinical improvement bar restored for add-on payments FY 2028.
- **EMA Breakthrough Device pilot opens (Apr 28),** Europe's parallel to FDA’s Breakthrough fast-track.

- **High Level Leadership changes at FDA continue,** including FDA Commissioner Martin Makary resigning May 12.
- **EU AI Act deal pauses machinery compliance not medtech.** Medtech stays dual-regulated under MDR + AI Act (May 7).
- **EUDAMED mandatory May 28.** EU device transparency and supply-chain visibility push intensifies.

Regulatory & Compliance

AI and supply chain action amid FDA changes

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INSIGHTS
REGULATORY & MARKET ACCESS

Regulatory & Market Access April '26

Global changes reshape medtech supply chain, quality, & AI rules

United States

LEADERSHIP TURNOVER AMID SPEED-TO-MARKET EXPANSIONS

- **Senior FDA leadership turnover continues.** Martin Makary resigned as head of FDA on May 12
- **Speed pathways open, while compliance tightens.** Real-Time Clinical Trial pilot launched Apr 28; FDA-CMS launch RAPID Coverage Pathway for TAP participation (Apr 23) accelerating coverage for some Breakthrough Devices; CMS proposes NTAP repeal for Breakthrough Devices (Apr 10) restoring substantial clinical improvement bar for add-on payments FY 28
- **New FDA quality rule fully operational.** US aligned with ISO 13485; inspectors have more access
- **FDA cyber compliance bar continues rising**. New FDA-MITRE technical frameworks for medical device cyber risk analysis and software transparency.

EU / EAA

EMA BREAKTHROUGH DEVICES PILOT LIVE & AI ACT RELIEF SKIPS MEDTECH

- **EU pauses AI Act compliance for industry but not for medtech (May 7).** New deal postpones high-risk AI deadlines to 2027/2028 & exempts machinery. Devices stay in scope, dual-regulated per MDR+AI Act.
- **EMA launches breakthrough device fast-track (Apr 28).** Europe's first answer to FDA's Breakthrough pathway. Phase I accepts Class III and high-risk Class IIb devices through May 22.
- **EU device total lifecycle traceability and supply-chain visibility push continues.** Device database (EUDAMED) becomes mandatory May 28; manufacturer incident reporting, supply-disruption notification, and classification rules all refreshed in April.

United Kingdom

INTERNATIONAL ALIGNMENT MOVES FORWARD

- **UK accelerates US regulatory alignment (Apr 7).** MHRA and FDA committed to exploring mutual recognition mechanisms for medical devices. Expands US-UK drugs partnership to medical devices.
- **UK consults on EU certification recognition (closed Apr 10).** Feeds UK's broader international reliance strategy, companies with approvals from the US, EU, Australia, or Canada gain streamlined UK pathways.
- **UK commits £3.6M to AI medical device sandbox (Apr 8).** 3-year DHSC funding through 2029 to advance AI.

Canada

US-ALIGNED PATHWAY SHIFTS MEDICAL DEVICE PATH TO MARKET

- **Canada's electronic submission system now mandatory.** All medical device license applications must use Health Canada's Regulatory Enrolment Process, paper filings no longer accepted.
- **Canadian submissions now share US infrastructure.** Health Canada adopted the same secure electronic gateway US sponsors use for FDA filings, operationally aligns Canada with FDA.
- **Canada updates AI medical device guidance.** Reinforces lifecycle expectations for AI/ML devices.

China

QUALITY ENFORCEMENT UP AS EXPORT PROGRAMS EXPAND

- **China issues 5 new device guidelines (Apr 9).** NMPA updated requirements for intravascular ultrasound, endoscopes, and others for international alignment.
- **China coverage modernization.** Shift to DRG payments, where bundled reimbursement affects total margins.
- **China launches 2026 device quality crackdown (Apr 8).** 70+ device categories under intensified inspection; serious non-compliance eligible for criminal charges.
- **China expands device export framework (May 1).** New two-tier certificate system enables export pathways.

Asia-Pacific (Japan, Australia, New Zealand, ASEAN)

FOCUS ON POST-MARKET COORDINATION

- **Australia continues to tighten post-market device enforcement.** Hospital adverse-event reporting penalties live since Mar 21, & software rules expand.
- **Japan continues to lead adaptive-AI device regulation via its IDATEN/PACMP system,** which permits pre-approved post-market changes for AI/ML software.
- **ASEAN regulatory reliance programs expand.** Malaysia & Thailand completed pilots & now operate medical device regulatory reliance for Class B, C, & D devices. New Zealand maintains TGA-aligned approach.

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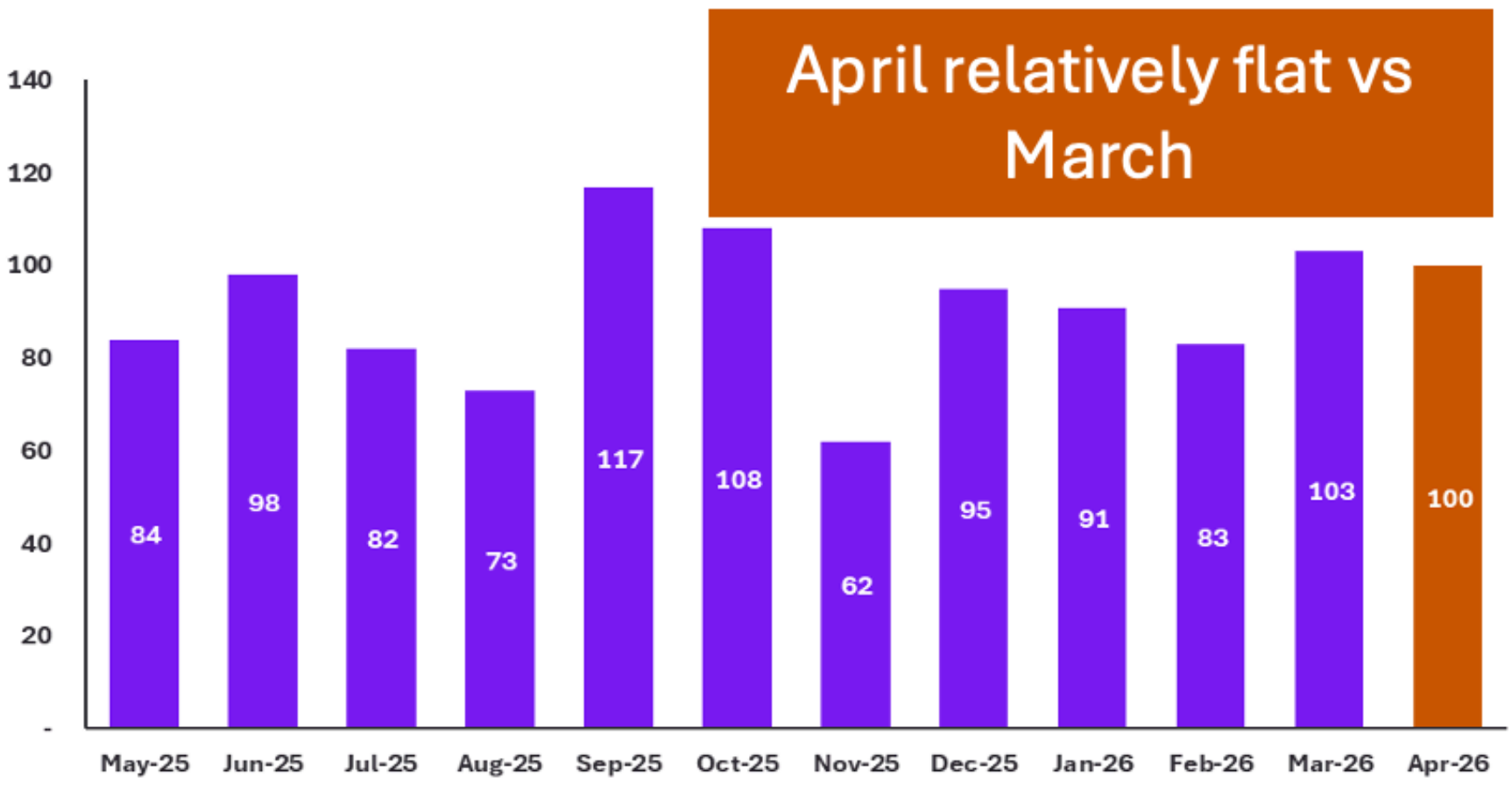
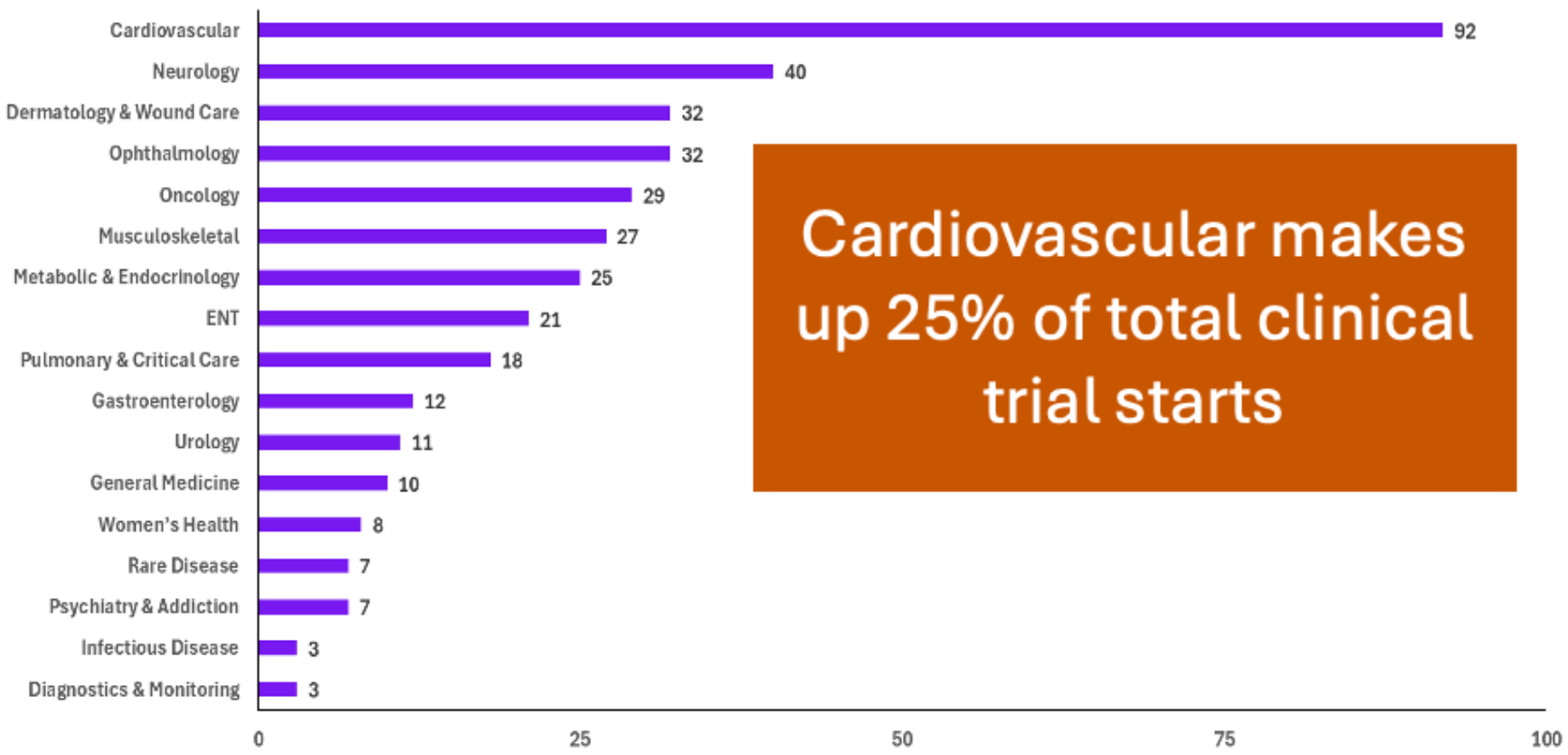
Clinical Trial Starts



April YTD Trial Starts by Therapeutic Area



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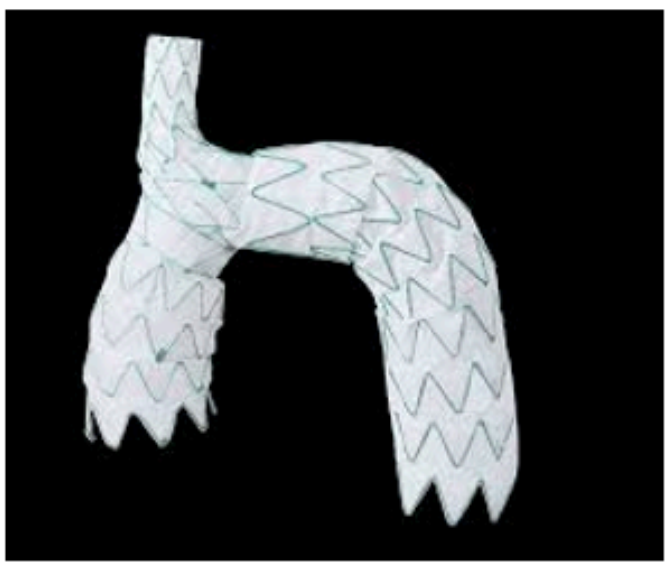
April ‘26 PMA Approval



ARTIVION

ENDOSPAN®

- NEXUS Aortic Arch Stent Graft System
- NEXUS is a branched endovascular stent graft system approved in the U.S. for the minimally invasive treatment of aortic arch disease, including chronic aortic dissections, a patient population that has historically had little treatment option but open-chest surgery.
- The approval entitles Artivion to exercise its option to acquire Endospan at any time within 90 days of receiving this notice of FDA approval.

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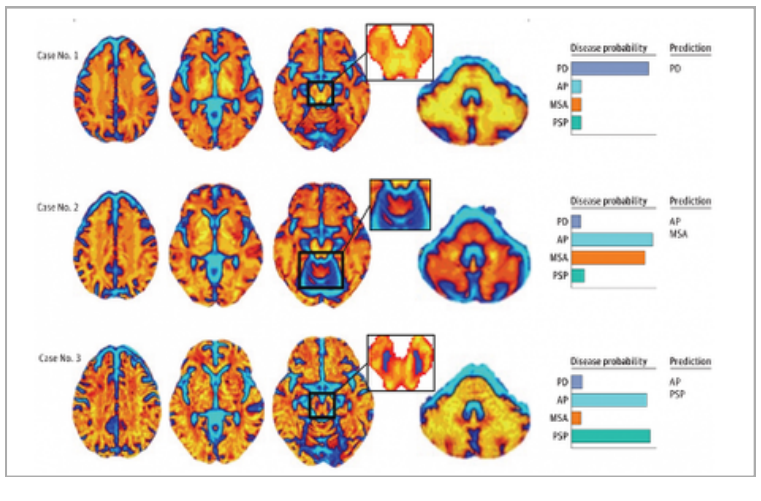
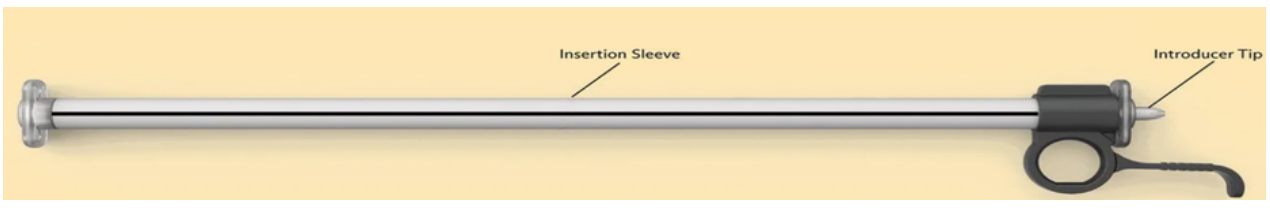
April ‘26 De Novo Approvals

- **XplantR Explant Tool** (by Hjarta Care)
- A first-of-its-kind medical device to aid in explanting EVAR devices
- Reduces suprarenal cross-clamp time, limiting the risk of end-organ failure and costly complications or readmission

- **Neuropacs** (by Automated Imaging Diagnostics, Inc.)
- A suite of AI-powered, imaging enabled software built specifically for neurodegenerative disease to:
  - Detect disease
  - Quantify neurodegeneration
  - Analyze clinical diagnostics
  - Improve clinical trial outcomes



- **Aurie System** (by Catybuddy, Inc.)
- A no-touch catheter made from the highest quality materials, is being designed to be reused up to 100 times with the Aurie Personal Disinfector



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April ‘26 HDE Approvals

Serenity Medical

- **Trade Name: River Stent System™**
- **Classification Name: Intracranial neurovascular stent**
- **Designed specifically for stenotic sinuses with several key advantages:**
  - Flexibility: ability to conform to the transverse-sigmoid sinus via a highly flexible material
  - Softness: important for both ease of placement and to conform to the sinus anatomy
  - Reduced Metal Surface Area: aims to minimize the risk of venous thrombosis
  - Variable Radial Force & Diameter: to adapt to the anatomy & physiology of the sigmoid & transverse sinuses
  - One is Greater Than Two: two stents increase the risk of cortical vein thrombosis

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