FDA's Digital Health Device Lists: Why the September 2026 Update Matters

A stakeholder briefing on the AI/ML, AR/VR, and sensor-based digital health technology (sDHT) device lists — CAHIR Innovators

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Definitions and Background

Before examining the FDA's specific device lists, it is worth clarifying three terms often used interchangeably in medtech conversation but that carry distinct regulatory weight: **digital health**, **medical device**, and the intersection the FDA actually regulates and tracks — digital health technology that meets the medical device definition.

Digital health is the broad umbrella. The FDA defines digital health technology (DHT) as "a system that uses computing platforms, connectivity, software, and/or sensors for health care and related uses." This spans mobile health apps, health IT, wearables, and telehealth, and it "spans a wide range of uses, from applications in general wellness to applications as a medical device." A step-counting fitness app and an FDA-cleared arrhythmia detector are both digital health technologies — only one is regulated as a device [web:8][web:14].

A **medical device** is the legal trigger. Under Section 201(h) of the FD&C; Act, a product becomes a device when it is intended for diagnosing, curing, mitigating, treating, or preventing disease, or intended to affect the structure or function of the body, without achieving its purpose through chemical action or metabolism. This test is technology-agnostic: software alone can meet it with no hardware component at all [web:7][web:19][web:6].

Digital health + medical device is the overlap the FDA's lists track. The FDA is explicit that "some DHTs may meet the definition of a medical device, while others do not" [web:11][web:16]. Software as a Medical Device (SaMD), AI/ML-enabled devices, AR/VR devices, and sensor-based wearables all sit in this overlap once they clear the 201(h) bar and receive marketing authorization — which is exactly the subset the three lists in this report enumerate, filtering out the much larger universe of unregulated wellness apps and consumer trackers.

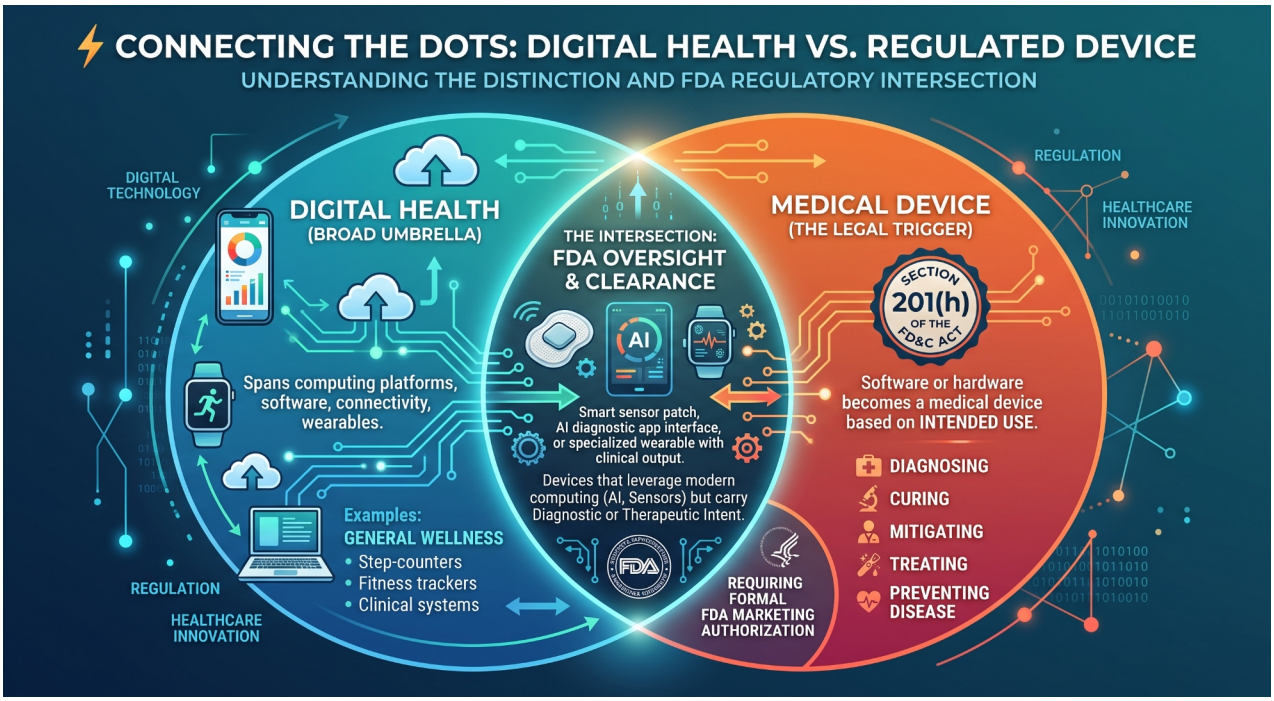

Figure 1: Digital health (broad umbrella) vs. medical device (Section 201(h) legal trigger) vs. their FDA-regulated intersection.

What Each List Covers

The **AI-Enabled Medical Device List** identifies devices whose FDA marketing-authorization summaries or classification reference AI-related terminology, per the FDA's Digital Health and AI Glossary. It is explicitly *not* comprehensive — captured primarily via keyword and classification review — but remains the closest public census of AI/ML-cleared devices. The list runs into the hundreds of entries, with new clearances added continuously through mid-2026. **Radiology**

dominates as the lead panel, followed by Cardiovascular, Neurology, and Gastroenterology-Urology. FDA also plans to explore tagging devices incorporating **foundation models and large language models (LLMs)**, giving generative-AI-enabled devices their own visibility layer in future updates [web:1].

The **AR/VR Medical Device List** tracks devices using augmented or virtual reality — surgical navigation overlays, mixed-reality spine/joint platforms, and VR-based pain management or behavioral-health therapeutics. Clearances cluster in **Neurology** (spine/ortho navigation) and Radiology (image-guided visualization), with recurring names such as Medacta's NextAR, Augmedics' xvision Spine, and AppliedVR's RelieVRx — the FDA-authorized VR chronic-pain therapeutic. The list dates to 2015 with accelerating clearance cadence through 2026 [web:2].

The **sDHT Medical Device List** is scoped to devices that are non- or minimally invasive, **wearable**, designed for continuous or spot-check monitoring, and usable in non-clinical settings like the home. Dating to 2014, it is dominated by **Cardiovascular** (ECG, arrhythmia, blood-pressure devices) and **Clinical Chemistry** (continuous glucose monitors from Dexcom, Abbott, Senseonics), plus a growing Neurology/sleep-monitoring segment. Consumer-adjacent entrants — Apple, Fitbit/Google, Samsung, Withings — appear alongside pure-play medtech wearable makers [web:3].

Comparative Snapshot

List	Scope Definition	Leading Panel(s)	Notable Entrants
AI/ML-Enabled Devices	Devices with AI-related terms in authorization summary or classification; keyword-based, not exhaustive	Radiology (dominant); Cardiovascular, Neurology, Gastroenterology-Urology	GE, Siemens, Philips, Aidoc, Viz.ai, Overjet, DeepHealth, Anumana
AR/VR Medical Devices	Devices using augmented or virtual reality overlays or immersive environments	Neurology (spine/ortho navigation); Radiology (visualization)	Medacta, Augmedics, AppliedVR, Brainlab, Surgical Theater
Sensor-Based Digital Health (sDHT)	Non/minimally invasive, wearable, continuous or spot-check monitoring, usable at home	Cardiovascular; Clinical Chemistry (CGM); growing Neurology/sleep segment	Dexcom, Abbott, Apple, Fitbit, Masimo, iRhythm, Empatica

Source: FDA Digital Health Center of Excellence device lists, accessed September 2026 [web:1][web:2][web:3].

Why This Matters to Stakeholders

Founders and product teams

The lists function as a live precedent database. A team building an imaging-AI triage tool, a wearable arrhythmia monitor, or an AR surgical-navigation product can identify comparable cleared devices, their product codes, panel assignments, and submission pathway (510(k), De Novo, or PMA supplement) — sharpening predicate selection and shortening Q-Submission preparation.

Investors and market-access analysts

Clearance velocity by category is a leading indicator of category maturity and competitive density. Radiology AI's continued dominance signals a crowding market where differentiation must shift toward workflow integration, reimbursement coding, and real-world performance data rather than novelty of use case. Steady cadence in cardiovascular and glucose-monitoring sDHT clearances signals durable payer and clinical demand.

Health systems, clinicians, and RA/QA leaders

The lists offer a transparency mechanism for verifying whether a device's AI, AR/VR, or sensor claims carry FDA marketing authorization — useful for procurement and patient-consent conversations, especially as generative-AI functionality enters clinical products. Because each list is keyword- or summary-derived rather than exhaustive, RA teams should treat absence from a list as inconclusive and cross-check against full 510(k)/De Novo/PMA database entries before drawing competitive or regulatory conclusions.

Practical Takeaways

- Benchmark early: before a Q-Submission, search the relevant list for cleared devices sharing your product code or intended use to inform predicate strategy and evidence expectations.
- Watch the LLM-tagging initiative: FDA's plan to tag foundation-model/LLM-enabled devices will materially change transparency expectations for generative-AI medtech products.
- Track category concentration, not just counts: Radiology's dominance in AI/ML and Cardiovascular/Clinical Chemistry's dominance in sDHT indicate where regulatory and payer coverage precedent is most mature.
- Use the lists as a conversation starter, not a compliance determination: each list explicitly disclaims comprehensiveness, so pair it with full database review and company-specific regulatory assessment.

Prepared by CAHIR-Innovators. Sources: FDA Digital Health Center of Excellence — What is Digital Health, Software as a Medical Device (SaMD), Digital Health Policy Navigator, Digital Health and AI Glossary, AI/ML-Enabled Medical Devices, Augmented Reality and Virtual Reality Medical Devices, and Sensor-Based Digital Health Technology Medical Devices lists (fda.gov), accessed September 2026. This summary is informational and does not constitute regulatory advice; company-specific submissions should be assessed against full FDA database entries and current guidance.