FDA REGULATORY BRIEF · 21 CFR 892.2080 (PRIMARY CODE QAS OR QFM)

From Single-Finding Filings to Multi-Indication CADt (2018-2026)

Empirical census of 132 primary-code FDA triage authorizations, anchored by a2z-Omni-Triage (K262765) and Aidoc CARE Multi-Triage.

Innolitics

N = 132 Authorizations · Feb 2018 to Nov 2026

132 Primary QAS / QFM

68.9% QAS (91) | 31.1% QFM

91 QAS, 41 QFM (1 De Novo) · 113.0d median

6 of 7 Dual Bundles in '25-26

'23 | 85.7% in 2025-26

All 5 filings with 5+ findings used QAS + QFM

26 claims* a2z 3-Device Sprint

7 Unified | 10 Abdo | 9* Omni

3 dual-code PCCP 510(k)s in 353 calendar days

6+ PCCPs Confirmed CADt PCCPs

2 in 2025 | 4 in 2026 (YTD)

K253265, K252366 + 4 in '26 · 0 of 4 pub. add findings

THREE-ERA REGULATORY SPINE: BUBBLE AREA SCALED TO FINDINGS / FILING

Single-code · Dual QAS+QFM · Dual + PCCP · Milestones evenly spaced · click any for FDA highlight

ERA 1 (2018-2021) · MOSTLY SINGLE-FINDING

- Feb 2018 · DEN170073 — Viz.ai ContaCT — Creates 892.2080 / QAS — 1
- Aug 2018 · K180647 — Aidoc BriefCase — 1st CADt 510(k) (ICH) — 1
- Mar 2019 · K183285 — CureMetrix cmTriage — 1st passive QFM code — 1

ERA 2 (2022-2024) · DUAL PIONEERS

- Mar 2023 · K222179 — Annalise CXR — 1st Dual QFM+QAS · 249d — 2
- Apr 2023 · K223240 — Annalise CTB — 4 ICH subtypes · 165d — 4

2018 to Apr 22, 2025: 0 filings >4 findings across first 104 clinical clearances (excl. K203508)

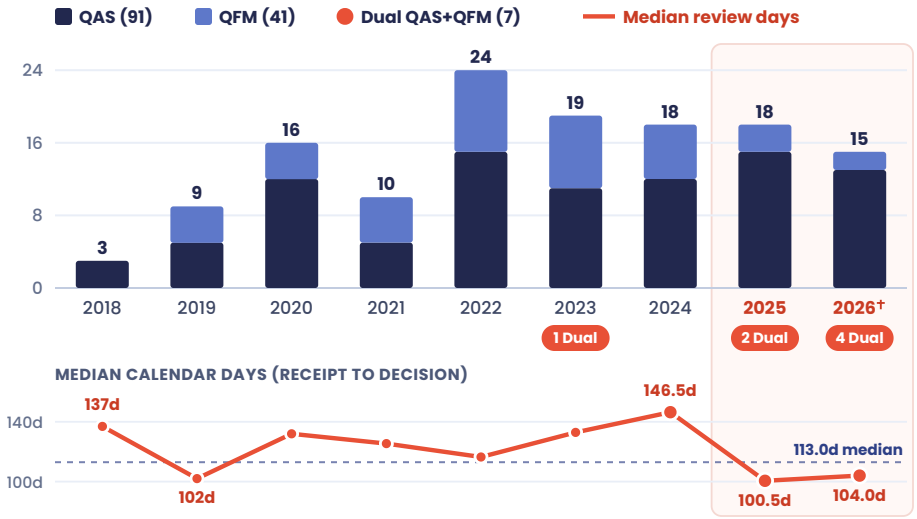
ERA 3 (2025-2026) · FOUNDATION CORES, MODULAR BUNDLES & PCCPs

- Apr 2025 · K250831 — Annalise CXR — Special 510(k) · 35d — 5
- Nov 2025 · K252366 — a2z-Unified — Dual + PCCP · 117d — 7
- Jan 2026 · K252970 — Aidoc CARE Body — Foundation CT · 112d — 11
- Feb 2026 · K253578 — Aidoc CARE CT — Dual QAS+QFM · 101d — 4
- Sep 2026 · K260906 — a2z-Abdo — Dual + PCCP · 181d — 10
- Nov 2026 · K262765 — a2z-Omni — Dual + PCCP · 100d — 9*

5 bundles hit 5-11 findings (all dual-code); K253265, K261085, K262301 single-code PCCPs not plotted

ANNUAL VOLUME & REVIEW-TIME TREND

†2026 YTD (Nov 28) · 2024 peak 146.5d → 100.5d / 104.0d



FOUNDER PLAYBOOK: FINDING-COUNT STRATEGY MAP

Findings per 510(k) (0 to 25+ scale)

STRATEGY	0	5	10	15	20	25+
Single-Finding v1 Aidoc examples: 56-205d	1 Narrow scope, but repeats user fees & hits hospital "point-solution fatigue."					
Modular Sprint OBSERVED 2025-26 · 100-181d Trad. · 35d Spec.	4 5 7 9* 10 11 — Click dots for FDA highlights					**4 to 11 findings / filing** Shared cohorts, dual QAS+QFM, staggered waves decouple holds.
Mega-Bundle 15 to 25+ · No precedent						**0 of 132 clearances** 1 weak rare finding can pause full file

SPONSOR ARCHITECTURE PACING (PRIMARY CODE)

Navy = single · Coral = dual · Ring = dual + PCCP

Aidoc	■■■