FDA 510(k) and De Novo Pathway for Autonomous Medical Devices

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510(k) and De Novo Frame

FDA 510(k) requires substantial-equivalence demonstration; De Novo provides framework for novel device classification. Both pathways increasingly engage emerging autonomous medical device operations.

Architecture Implications

Autonomous medical-device clearance requires structural defensibility for incident reconstruction, safety demonstration, and emerging post-market surveillance.

Architectural Mapping

Stage-gated commitment supports phase-decomposed safety case. Reversibility classification supports risk analysis. Composite admissibility supports multi-authority autonomous-medical operations.

FDA Trajectory

FDA emerging autonomous medical device pathway development and emerging FDA PCCP integration push toward structurally-supported architecture.