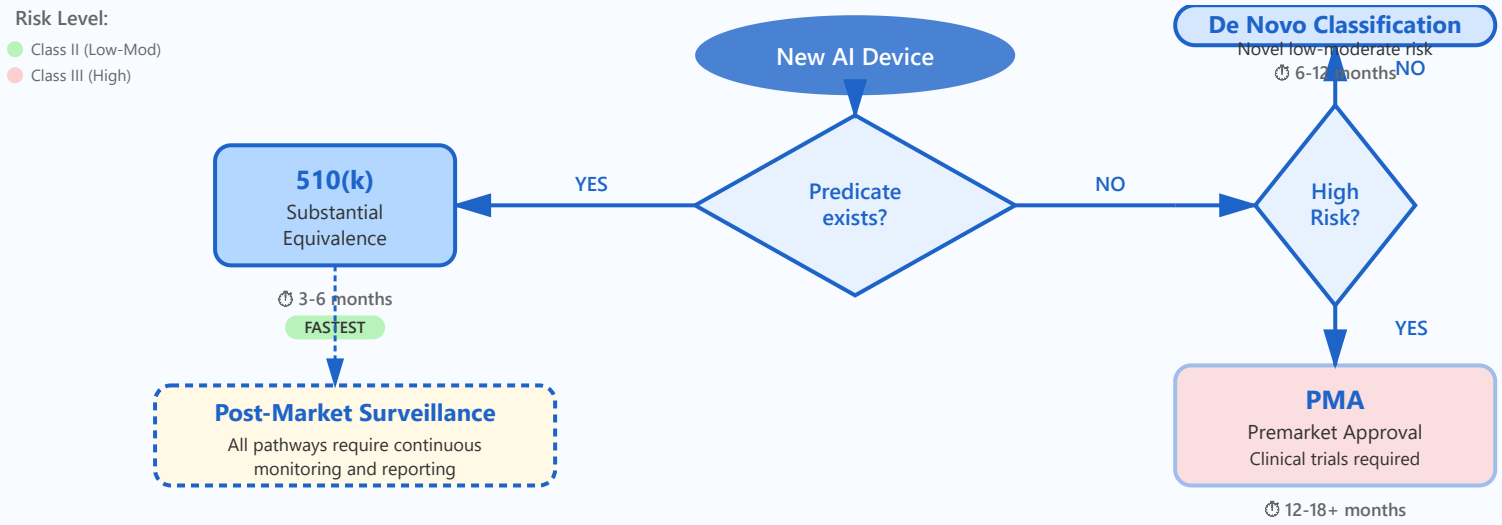
FDA Approval Process

Regulatory Pathways for AI/ML Medical Devices



510(k) Pathway

Substantial equivalence to existing device. Fastest route, ~3-6 months if predicate exists

De Novo Classification

Novel low-to-moderate risk devices. Creates new device category, ~6-12 months

PMA Requirements

Premarket Approval for high-risk devices. Most rigorous, requires clinical trials

Software Modifications

When algorithm changes require new submission. Predetermined change control plans

Real-World Surveillance

Post-market monitoring. Detect performance drift or adverse events