FDA Predetermined Change Control Plans for Surgical Autonomy

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The PCCP Framework

FDA finalized the PCCP guidance in 2024, establishing how AI/ML-enabled devices can be approved with pre-specified modification protocols rather than requiring re-submission for each model update. The framework makes continuously-improving AI systems regulatorily tractable for the first time.

PCCP-eligible systems must demonstrate, structurally, the modification scope, the testing protocol, and the impact assessment for each pre-specified change. The structural demonstration is where current architectures struggle.

What PCCP Structurally Requires

The pre-specified change must be bounded by reversibility classification. The testing protocol must produce credentialed evidence. The impact assessment must operate against architectural lineage. None of these are operationally heavy if the architecture supports them; all of them are operationally heavy if the architecture doesn't.

Where Governed Actuation Maps

Reversibility classifier maps directly to PCCP modification scope. Stage-gated commitment maps to the structurally-distinct testing requirements at different commitment levels. Composite admissibility maps to the multi-authority approval structure.

Operators that adopt the architecture gain PCCP-eligibility-by-construction.

Competitive Position Under PCCP

First-mover advantage on PCCP-architectural compliance is significant. Surgical-robotics OEMs that demonstrate PCCP-class architectural support gain regulatory pathway clarity that platform-only competitors cannot match.

The patent positions the architectural substrate at exactly the layer FDA's emerging PCCP enforcement increasingly requires.