

Maximum Pressure. No Margin for Error.

How the Commercial Operating System™ Delivered Early FDA Clearance for a First-in-Category Product

Organization	Mid-size publicly traded medtech company — specialty device portfolio in a high-growth chronic disease category
The Situation	Commercial-stage organization managing a multi-hundred-million dollar franchise across three products at different lifecycle stages: a mature platform, an advanced next-generation system, and a first-in-category product approaching regulatory submission
Timeline	Multi-year engagement (approx. 2.5 years) from governance buildout through FDA clearance and commercial scale

The stakes: A multi-hundred-million-dollar franchise and a first-in-category product launch were both on the line. Miss the regulatory window and the commercial buildout stalls. Lose alignment across 50+ people mid-submission and the launch timeline slips — publicly, with a board and investors watching. There was no version of "we'll fix governance after the launch." The operating system had to be built while the machine was already running.

BEFORE → AFTER

BEFORE	→	AFTER
Decisions re-opened across forums	→	Decisions resolved at the defined level
No clear accountability across the franchise	→	Explicit decision rights mapped across 50+ person team
Fragmented reporting — no board-ready signal	→	Board-ready KPI system with real-time franchise visibility
Commercial org structure informal and unmapped	→	Salesforce & org architecture aligned to three-product franchise

THE OUTCOMES

<p>Early Clearance On-time regulatory submission & early clearance for the first-in-category product — on timeline, no executive re-litigation</p>	<p>15K+ New customer starts driven across the franchise at all lifecycle stages</p>	<p>7-Figures Revenue generated via primary care pilot — lean team model, pre-full commercialization</p>	<p>50+ Cross-functional team operating with aligned governance architecture by close of engagement</p>
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The regulatory clearance outcome is the headline — but it is not the whole story. Early clearance for the first-in-category product was the result of a commercial organization that had built the governance infrastructure to execute without losing velocity. The submission stayed on timeline because decisions that could have stalled it were resolved at the right level, with the right people, without requiring executive re-litigation at each turn.

"The most important outcome wasn't a single metric. It was that by the close of the engagement, the organization had a commercial operating system it could run — not just a launch it had survived."

IS THIS YOUR ORGANIZATION'S INFLECTION POINT?

Most organizations don't recognize this moment until a launch is already at risk. By then, the symptoms are visible — slowed decisions, executive re-litigation, fractured execution — but the root cause is structural.

The **Commercial Operating System™ Diagnostic** makes those gaps visible *before they surface* — delivering a scored view across all five governance domains.

If you're approaching a critical inflection point — regulatory, launch, or scale — this is where the work starts.

Take the diagnostic →
scorecard.alexanderjamison.com

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