

AI 360 Research Brief

Paper title: AI-Enabled Medical Devices and Post-Market Safety: Empirical Evidence and Prescriptions for Validation Resource Allocation

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Brief overview of the research:

Using FDA data on 26,535 medical devices cleared from 2004-2024, we examine whether AI-enabled devices face different post-market safety risks. AI-enabled devices show about 2.5 times the hazard of first recall, driven by design and software failures. We translate these patterns into a decision support model for allocating validation resources.

Why this research matters:

AI-enabled medical devices are expanding rapidly, but conventional validation and oversight practices were largely developed for non-AI technologies. Our findings suggest that AI changes not only the level of post-market risk but also where that risk originates: design, software, algorithms, and use contexts matter more than traditional manufacturing defects. The elevated recall hazard is stronger under third-party review and weaker among manufacturers with greater research capability. Our results suggest that manufacturers and regulators should tailor validation resources and review capacity to AI-specific risk profiles, emphasizing design and software validation while preserving essential manufacturing controls.