

FDA 510(k) Clearance: The Regulatory Standard for Imaging Platforms

Not all technology platforms are created equal when it comes to regulatory standards. MERIT's EXCELSIOR™ cloud-based software platform is classified as Software as a Medical Device (SaMD) and is developed in alignment with regulatory expectations that apply to software performing measurement functions in clinical research. Because EXCELSIOR is used for detection, measurement, and quantitative analysis of medical image findings in clinical trials, it requires—and holds—FDA 510(k) clearance.

EXCELSIOR is cleared as a Class II medical device (K#220929), a regulatory designation specifically tied to software that directly performs measurement functions influencing clinical decision making. Even a simple line measurement on a medical image constitutes a directly performed measurement function and, under FDA guidance, should be addressed under SaMD 510(k) requirements—**an obligation many platforms overlook, but one MERIT treats as standard practice.**

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With 510(k) clearance, EXCELSIOR is subject to the same design controls, verification and validation standards, production practices, and post market requirements that govern traditional medical device manufacturers. This regulatory rigor ensures that any measurement or quantitative output generated by the software meets FDA expectations for accuracy, consistency, and auditability.



Because EXCELSIOR is an FDA cleared measurement device, clinical trial **sponsors benefit from a technology environment built within a fully regulated, 21 CFR 820 compliant framework.** This foundation strengthens confidence in the following critical factors in ophthalmology, radiology, and other measurement-driven therapeutic areas:



Traceability of measurement data

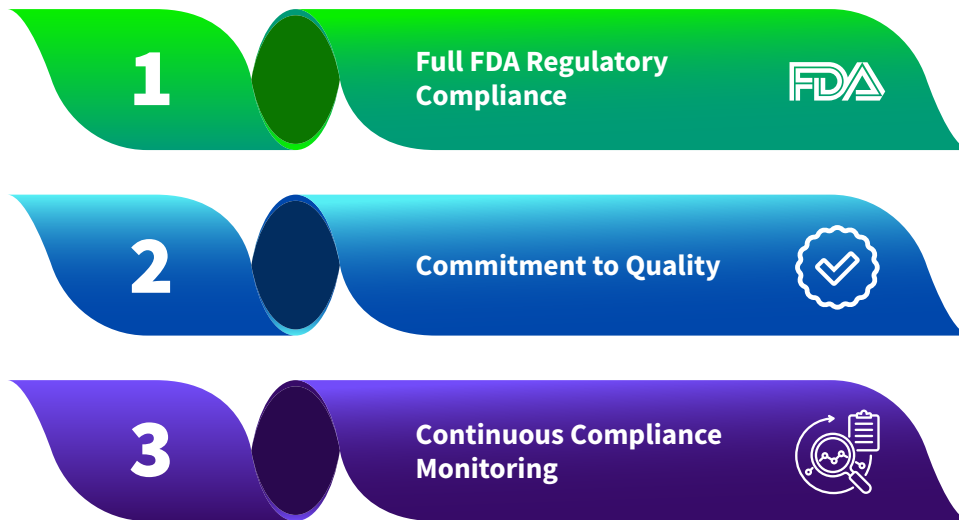


Integrity of image-based endpoints



Readiness for global regulatory submissions

3 Benefits of FDA 510(k) Registration



- 1 Full FDA Regulatory Compliance:** Customers gain confidence knowing that EXCELSIOR has undergone regulatory review and clearance by the FDA.
- 2 Commitment to Quality:** Clients can trust that the platform adheres to high-quality standards, reducing the risk of errors or malfunctions.
- 3 Continuous Compliance Monitoring:** Clients benefit from ongoing compliance monitoring and updates to ensure that the platform continues to meet evolving regulatory standards.