MERIT INFO SHEET

Why FDA 510(k) Clearance Matters:

Safeguarding Data and Advancing Innovation

Not all technology platforms are created equal. MERIT's EXCELSIOR™ system not only increases accuracy and efficiency by providing a suite of advanced endpoint analysis tools, but it also provides the regulatory assurance of FDA 510(k) clearance. EXCELSIOR is cleared with the FDA as a Class II medical device with specific indications for managing ophthalmic and radiological clinical trial data. **FDA 510(k) clearance offers:**

Regulatory Assurance:

Customers can have confidence that EXCELSIOR has undergone regulatory review and clearance by the FDA. This assurance of compliance with regulatory standards can be important in avoiding potential regulatory issues.

Quality & Safety:

FDA clearance indicates that EXCELSIOR has undergone rigorous evaluation and testing to demonstrate its safety and effectiveness. Clients can trust that the platform adheres to high-quality standards, reducing the risk of errors or malfunctions.

Customer Support & Training:

Companies that obtain 510(k) clearance typically invest in providing robust customer support and training programs. Customers can benefit from access to knowledgeable support staff and resources to help them optimize their use of the platform.

Continuous Compliance Monitoring:

Companies that have obtained FDA clearance for their technology are committed to maintaining compliance with regulatory requirements. Clients can benefit from ongoing compliance monitoring and updates to ensure that the platform continues to meet evolving regulatory standards.

Clients and partners who use MERIT's 510(k) approved EXCELSIOR will discover a reliable, compliant, and effective solution for managing medical imaging data.

MERIT

Your Clinical Endpoint Expert

Connect with us to learn more about how our expertise and approach can support bringing your product to market on-time and on-budget. Your success is our priority.

meritcro.com | | **E: Info@meritcro.com** | **P: (608) 284-8810**