

**K850213 ISOCONTROL SERUM CK-MB**Mar 5, 1985  
49 days to decisionK850213 · Product code: **JJT** · Chemistry  
Source: <https://www.510kdatabase.net/k850213/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Controls (assayed And Unassayed) (JJT)
Date received	Jan 15, 1985
Decision date	Mar 5, 1985
Days to decision	49 days
Third-party review	No

**APPLICANT**

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Company	<b>Sclavo, Inc.</b>
Location	Mchenry, IL, US
Contact	DEBRA HOFMEISTER
510(k) history	82 submissions · 82 cleared · 1977-1992

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k850213/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 29, 2026