

**K850480 OVU STICK SELF-TEST -MODIFICATION**Mar 5, 1985  
34 days to decisionK850480 · Product code: **CEP** · Chemistry  
Source: <https://www.510kdatabase.net/k850480/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Luteinizing Hormone (CEP)
Date received	Jan 30, 1985
Decision date	Mar 5, 1985
Days to decision	34 days
Third-party review	No

**APPLICANT**

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Company	<b>Monoclonal Antibodies, Inc.</b>
Location	Mchenry, IL, US
Contact	MICHAEL C MALONEY
510(k) history	14 submissions · 14 cleared · 1982-1988

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k850480/>, 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 30, 2026