

**K103376 ELITECH CLINICAL SYSTEMS CREATINNE PAP SL  
MODEL CRSL-0250, CLITECH CLINICAL SYSTEMS ELICAL 2  
MODEL CALI-0580, ELITECH CL**Nov 18, 2011  
366 days to decisionK103376 · Product code: JFY · Chemistry  
Source: <https://www.510kdatabase.net/k103376/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzymatic Method, Creatinine (JFY)
Date received	Nov 17, 2010
Decision date	Nov 18, 2011
Days to decision	366 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Seppim S.A.S.</b>
Location	Bothell, WA, US
Contact	DEBRA K HUTSON
510(k) history	6 submissions · 6 cleared · 2010-2011

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k103376/> 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 16, 2026