

**K102706 CKMB UDR ASSAY**Aug 19, 2011  
333 days to decisionK102706 · Product code: **JHS** · Chemistry  
Source: <https://www.510kdatabase.net/k102706/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Differential Rate Kinetic Method, Cpk Or Isoenzymes (JHS)
Date received	Sep 20, 2010
Decision date	Aug 19, 2011
Days to decision	333 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>SENTINEL CH. SpA</b>
Location	Milano, IT
Contact	FABIO ROTA
510(k) history	12 submissions · 12 cleared · 2007-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k102706/> 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 May 26, 2026