

**K885023 CHOLESTEROL TEST ITEM NUMBER: SR1011**Feb 17, 1989  
74 days to decisionK885023 · Product code: **CHH** · Chemistry  
Source: <https://www.510kdatabase.net/k885023/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzymatic Esterase--oxidase, Cholesterol (CHH)
Date received	Dec 5, 1988
Decision date	Feb 17, 1989
Days to decision	74 days
Third-party review	No

**APPLICANT**

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Company	<b>Em Diagnostic Systems, Inc.</b>
Location	Walker, MI, US
Contact	G BENTLEY
510(k) history	288 submissions · 288 cleared · 1984-1994

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k885023/>; 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 14, 2026