

K935136 CHOLESTEROL (CHOL) TEST ITEM NO. 65410Dec 16, 1993
49 days to decisionK935136 · Product code: **CHH** · Chemistry
Source: <https://www.510kdatabase.net/k935136/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzymatic Esterase--oxidase, Cholesterol (CHH)
Date received	Oct 28, 1993
Decision date	Dec 16, 1993
Days to decision	49 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Em Diagnostic Systems, Inc.
Location	Walker, MI, US
Contact	CAROL FAULKNER
510(k) history	288 submissions · 288 cleared · 1984-1994

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