

K843327 SYSTEMATE CHOLESTEROL 67222Sep 14, 1984
18 days to decisionK843327 · Product code: **CHH** · Chemistry
Source: <https://www.510kdatabase.net/k843327/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzymatic Esterase--oxidase, Cholesterol (CHH)
Date received	Aug 27, 1984
Decision date	Sep 14, 1984
Days to decision	18 days
Third-party review	No

APPLICANT

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

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Device record: <https://www.510kdatabase.net/k843327/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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