

K854010 FRUCTOSAMINE TEST (ROCHE)Dec 22, 1987
813 days to decisionK854010 · Product code: **LCP** · Chemistry
Source: <https://www.510kdatabase.net/k854010/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Sep 30, 1985
Decision date	Dec 22, 1987
Days to decision	813 days
Third-party review	No
Combination product	No
PCCP authorized	No

APPLICANT

Company	Roche Diagnostic Systems, Inc.
Location	Mchenry, IL, US
Contact	GRIFFIN FITZGERALD
510(k) history	296 submissions · 296 cleared · 1983-1999

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Device record: <https://www.510kdatabase.net/k854010/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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