

K843109 ROCHE REAGENT FOR ASTNov 5, 1984
90 days to decisionK843109 · Product code: **CIT** · Chemistry
Source: <https://www.510kdatabase.net/k843109/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nadh Oxidation/nad Reduction, Ast/sgot (CIT)
Date received	Aug 7, 1984
Decision date	Nov 5, 1984
Days to decision	90 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/k843109/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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