

K850807 COBAS FP REAGENTS FOR CARBAMAZEPINEMar 22, 1985
23 days to decisionK850807 · Product code: **KLT** · Chemistry
Source: <https://www.510kdatabase.net/k850807/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Carbamazepine (KLT)
Date received	Feb 27, 1985
Decision date	Mar 22, 1985
Days to decision	23 days
Third-party review	No
Combination product	No
PCCP authorized	No

APPLICANT

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

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Device record: <https://www.510kdatabase.net/k850807/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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