

**K964765 CHIRON DIAGNOSTICS ACS: 180 CARBAMAZEPINE
ASSAY**Feb 14, 1997
79 days to decisionK964765 · Product code: **KLT** · Toxicology
Source: <https://www.510kdatabase.net/k964765/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Carbamazepine (KLT)
Date received	Nov 27, 1996
Decision date	Feb 14, 1997
Days to decision	79 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Chiron Diagnostics Corp.
Location	Medfield, MA, US
Contact	William J Pignato
510(k) history	20 submissions · 20 cleared · 1997-1999

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k964765/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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