

K863842 SERALYZER ARIS CARBAMAZEPINE STRIPS/MODU/CALI/CONT

Jan 14, 1987
105 days to decision

K863842 · Product code: **KLT** · Toxicology
Source: <https://www.510kdatabase.net/k863842/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Carbamazepine (KLT)
Date received	Oct 1, 1986
Decision date	Jan 14, 1987
Days to decision	105 days
Third-party review	No

APPLICANT

Company	Miles Laboratories, Inc.
Location	Mchenry, IL, US
Contact	JOHN H ENGELMANN
510(k) history	158 submissions · 158 cleared · 1976-1988

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Device record: <https://www.510kdatabase.net/k863842/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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