

K980283 VITROS CHEMISTRY PRODUCTS CRBM SLIDESFeb 25, 1998
30 days to decisionK980283 · Product code: **KLT** · Chemistry
Source: <https://www.510kdatabase.net/k980283/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Carbamazepine (KLT)
Date received	Jan 26, 1998
Decision date	Feb 25, 1998
Days to decision	30 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Johnson & Johnson Clinical Diagnostics, Inc.
Location	Rochester, NY, US
Contact	CHARLES C MORGANSON
510(k) history	33 submissions · 33 cleared · 1995-1998

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