

K123518 ABBOTT CARBAMAZEPINE ASSAYJun 5, 2013
203 days to decisionK123518 · Product code: **KLT** · Toxicology
Source: <https://www.510kdatabase.net/k123518/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Carbamazepine (KLT)
Date received	Nov 14, 2012
Decision date	Jun 5, 2013
Days to decision	203 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Microgenics Corporation
Location	Fremont Blvd., CA, US
Contact	KAREN LEE
510(k) history	21 submissions · 20 cleared · 2009-2024

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