

**K151578 Carbamazepine Gen 4**Oct 22, 2015  
133 days to decisionK151578 · Product code: **KLT** · Toxicology  
Source: <https://www.510kdatabase.net/k151578/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Carbamazepine (KLT)
Date received	Jun 11, 2015
Decision date	Oct 22, 2015
Days to decision	133 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Roche Diagnostics Operations (Rdo)</b>
Location	Indianapolis, IN, US
Contact	David Tribbett
510(k) history	14 submissions · 14 cleared · 2014-2020

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k151578/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 31, 2026