

**K200363 Quidel Triage® TOX Drug Screen, 94600**Mar 11, 2020  
26 days to decisionK200363 · Product code: **DKZ** · Toxicology  
Source: <https://www.510kdatabase.net/k200363/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Enzyme Immunoassay, Amphetamine (DKZ)
Date received	Feb 14, 2020
Decision date	Mar 11, 2020
Days to decision	26 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Quidel Cardiovascular, Inc.</b>
Location	San Deigo, CA, US
Contact	Rachael S Williamson
510(k) history	2 submissions · 2 cleared · 2019-2020

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k200363/> 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 June 18, 2026