

**K171403 OralTox Oral Fluid Drug Test**Feb 2, 2018  
266 days to decisionK171403 · Product code: **DJC** · Toxicology  
Source: <https://www.510kdatabase.net/k171403/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thin Layer Chromatography, Methamphetamine (DJC)
Date received	May 12, 2017
Decision date	Feb 2, 2018
Days to decision	266 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Premier Biotech, Inc.</b>
Location	Minneapolis, MN, US
Contact	Jacqueline Gale
510(k) history	2 submissions · 2 cleared · 2018-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k171403/> 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