

**K181305 OralTox Oral fluid Drug Test**Sep 20, 2018  
126 days to decisionK181305 · Product code: **DJC** · Toxicology  
Source: <https://www.510kdatabase.net/k181305/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thin Layer Chromatography, Methamphetamine (DJC)
Date received	May 17, 2018
Decision date	Sep 20, 2018
Days to decision	126 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k181305/> 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 23, 2026