

**K183048 Quantisal II Oral Fluid Collection Device**Jul 29, 2019  
269 days to decisionK183048 · Product code: **PJD** · Chemistry  
Source: <https://www.510kdatabase.net/k183048/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oral Fluid Drugs Of Abuse And Alcohol Test Specimen Collection Device (PJD)
Date received	Nov 2, 2018
Decision date	Jul 29, 2019
Days to decision	269 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Immunalysis Corporation</b>
Location	Mchenry, IL, US
Contact	Wenyong (Jessica) Zhu
510(k) history	50 submissions · 50 cleared · 1978-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k183048/> 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 28, 2026