

K223781 Quantisal™ II Oral Fluid Collection DeviceJul 28, 2023
224 days to decisionK223781 · Product code: **PJD** · Chemistry
Source: <https://www.510kdatabase.net/k223781/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oral Fluid Drugs Of Abuse And Alcohol Test Specimen Collection Device (PJD)
Date received	Dec 16, 2022
Decision date	Jul 28, 2023
Days to decision	224 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Immunalysis Corporation
Location	Mchenry, IL, US
Contact	Shubhajit Mitra
510(k) history	50 submissions · 50 cleared · 1978-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k223781/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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