

K232898 Quantisal™ Oral Fluid Collection DeviceNov 21, 2023
64 days to decisionK232898 · Product code: **PJD** · Chemistry
Source: <https://www.510kdatabase.net/k232898/>**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 | Sep 18, 2023 |
| Decision date | Nov 21, 2023 |
| Days to decision | 64 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/k232898/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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