

K200801 Quantisal Oral Fluid Collection Device

Jul 28, 2020
123 days to decision

K200801 · Product code: **PJD** · Chemistry
Source: <https://www.510kdatabase.net/k200801/>

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	Mar 27, 2020
Decision date	Jul 28, 2020
Days to decision	123 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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