

## **K201228 Psychomedics Homogeneous Enzyme Immunoassay for Cocaine in Hair**

Jun 25, 2021  
414 days to decisionK201228 · Product code: **JXO** · Toxicology  
Source: <https://www.510kdatabase.net/k201228/>

### **SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Cocaine (JXO)
Date received	May 7, 2020
Decision date	Jun 25, 2021
Days to decision	414 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

### **APPLICANT**

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Company	<b>Psychomedics Corporation</b>
Location	Culver City, CA, US
Contact	Neil Stowe
Website	<a href="http://psychomedics.com/">http://psychomedics.com/</a>
510(k) history	7 submissions · 7 cleared · 2017-2022

Psychomedics Corporation is a hair drug testing laboratory headquartered in Dallas, Texas, with a manufacturing facility in Culver City, California. The company pioneered commercially-available hair drug testing in 1986 and specializes in toxicology testing for substance detection. Psychomedics has received FDA 510(k) clearances from total submissions between 2017 and 2022. All submissions focused on toxicology devices, including homogeneous enzyme immunoassay and microplate enzyme immunoassay systems for detecting drugs in hair samples. The company's cleared devices targ...