

K212952 Psychomedics Homogeneous Enzyme Immunoassay (HEIA) for Phencyclidine in Hair

Apr 18, 2022
214 days to decisionK212952 · Product code: **LCM** · Toxicology
Source: <https://www.510kdatabase.net/k212952/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Phencyclidine (LCM)
Date received	Sep 16, 2021
Decision date	Apr 18, 2022
Days to decision	214 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Psychomedics Corporation
Location	Culver City, CA, US
Contact	Neil Stowe
Website	http://psychomedics.com/
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...