

K192517 Psychomedics Microplate EIA for Cotinine in HairApr 22, 2020
222 days to decisionK192517 · Product code: **MKU** · Toxicology
Source: <https://www.510kdatabase.net/k192517/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Nicotine And Nicotine Metabolites (MKU)
Date received	Sep 13, 2019
Decision date	Apr 22, 2020
Days to decision	222 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Psychomedics Corporation
Location	Culver City, CA, US
Contact	Virginia Hill
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...

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