

K201326 Psychomedics Homogeneous Enzyme Immunoassay (HEIA) for Opiates in Hair, Psychomedics Homogeneous Enzyme Immunoassay (HEIA) for Oxycodone in Hair

Jul 27, 2021
434 days to decision

K201326 · Product code: **DJG** · Toxicology
Source: <https://www.510kdatabase.net/k201326/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Opiates (DJG)
Date received	May 19, 2020
Decision date	Jul 27, 2021
Days to decision	434 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...