

K163590 Psychemedics Microplate EIA for Benzodiazepines in Hair

Sep 15, 2017
269 days to decisionK163590 · Product code: **JXM** · Toxicology
Source: <https://www.510kdatabase.net/k163590/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Enzyme Immunoassay, Benzodiazepine (JXM) |
| Date received | Dec 20, 2016 |
| Decision date | Sep 15, 2017 |
| Days to decision | 269 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Psychemedics Corporation |
| Location | Culver City, CA, US |
| Contact | Virginia Hill |
| Website | http://psychemedics.com/ |
| 510(k) history | 7 submissions · 7 cleared · 2017-2022 |

Psychemedics 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. Psychemedics 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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Device record: <https://www.510kdatabase.net/k163590/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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