

K152551 First Sign® Drug of Abuse Buprenorphine Cup Test, First Sign® Drug of Abuse Buprenorphine Dip Card Test, First Sign® Drug of Abuse Butalbital Cup Test, First Sign® Drug of Abuse Butalbital Dip Card Test, First Sign® Drug of Abuse Morphine Cup Test, First Sign® Drug of Abuse Morphine Dip Card Test.Nov 9, 2015
62 days to decisionK152551 · Product code: DJG · Toxicology
Source: <https://www.510kdatabase.net/k152551/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Enzyme Immunoassay, Opiates (DJG) |
| Date received | Sep 8, 2015 |
| Decision date | Nov 9, 2015 |
| Days to decision | 62 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | W.H.P.M., Inc. |
| Location | Beverly, MA, US |
| Contact | JOHN WAN |
| 510(k) history | 14 submissions · 14 cleared · 2001-2022 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k152551/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026