

**K142855 Omega Laboratories Hair Drug Screening Assay
Methamphetamine (Meth) and -3,
4-methylenedioxymethamphetamine (MDMA)**Jul 28, 2015
301 days to decisionK142855 · Product code: **DKZ** · Toxicology
Source: <https://www.510kdatabase.net/k142855/>**SUBMISSION DETAILS**

| | |
|-----------------------|---------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Enzyme Immunoassay, Amphetamine (DKZ) |
| Date received | Sep 30, 2014 |
| Decision date | Jul 28, 2015 |
| Days to decision | 301 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Omega Laboratories, Inc. |
| Location | South Lyon, MI, US |
| Contact | William Corl |
| 510(k) history | 9 submissions · 9 cleared · 2010-2015 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k142855/> 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 June 4, 2026