

K033299 ACON MAMP ONE STEP METHAMPHETAMINE TEST STRIP AND TEST DEVICEDec 12, 2003
59 days to decisionK033299 · Product code: LAF · Toxicology
Source: <https://www.510kdatabase.net/k033299/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Gas Chromatography, Methamphetamine (LAF) |
| Date received | Oct 14, 2003 |
| Decision date | Dec 12, 2003 |
| Days to decision | 59 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | ACON Laboratories, Inc. |
| Location | San Diego, CA, US |
| Contact | EDWARD TUNG |
| Website | http://www.aconlabs.com/ |
| 510(k) history | 85 submissions · 85 cleared · 1998-2025 |

ACON Laboratories, Inc. is a global medical device manufacturer headquartered in San Diego, California. The company develops and manufactures diagnostic and point-of-care testing devices for hospitals, clinical laboratories, physician offices, blood banks, pharmacies, and veterinary clinics. ACON operates in over 130 countries and maintains FDA-registered manufacturing facilities with ISO 13485 certification. ACON has received FDA 510(k) clearances from total submissions since 1998, with no denied submissions. The company specializes in chemistry devices, including blood ...