

**K010841 ACON COC ONE STEP COCAINE TEST STRIP, ACON
COC ONE STEP COCAINE TEST DEVICE**Jul 9, 2001
110 days to decisionK010841 · Product code: **DIO** · Toxicology
Source: <https://www.510kdatabase.net/k010841/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Enzyme Immunoassay, Cocaine And Cocaine Metabolites (DIO) |
| Date received | Mar 21, 2001 |
| Decision date | Jul 9, 2001 |
| Days to decision | 110 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | ACON Laboratories, Inc. |
| Location | San Diego, CA, US |
| Contact | ROBERT HUDAK |
| 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 ...