

K142543 Mission U120 Ultra Urine Analyzer, Mission Liquid Urine Controls, Mission Liquid Diptube Urine ControlMay 11, 2015
243 days to decisionK142543 · Product code: **KQO** · Chemistry
Source: <https://www.510kdatabase.net/k142543/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Automated Urinalysis System (KQO) |
| Date received | Sep 10, 2014 |
| Decision date | May 11, 2015 |
| Days to decision | 243 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | ACON Laboratories, Inc. |
| Location | San Diego, CA, US |
| Contact | Qiyi Xie |
| 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 ...