FDA 510(k) Premarket Notification

**CLEARED**

# K032661 ACON QUICK-CHECK II HOME PREGNANCY TEST DEVICE (CASSETTE)

Oct 14, 2003
47 days to decision

K032661 · Product code: **LCX** · Chemistry
Source: https://www.510kdatabase.net/k032661/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Kit, Test, Pregnancy, Hcg, Over The Counter (LCX) |
| Date received | Aug 28, 2003 |
| Decision date | Oct 14, 2003 |
| Days to decision | 47 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 ...