

**K993317 ACON HCG ONE STEP PREGNANCY TEST DEVICE
(URINE)**Dec 1, 1999
58 days to decisionK993317 · Product code: JHI · Chemistry
Source: <https://www.510kdatabase.net/k993317/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Oct 4, 1999
Decision date	Dec 1, 1999
Days to decision	58 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	ACON Laboratories, Inc.
Location	San Diego, CA, US
Contact	NORA C.R. YORK
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 ...

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Device record: <https://www.510kdatabase.net/k993317/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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