

K003557 ACON THC ONE STEP MARIJUANA TEST STRIP(URINE)Mar 15, 2001
118 days to decisionK003557 · Product code: LDJ · Toxicology
Source: <https://www.510kdatabase.net/k003557/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Cannabinoids (LDJ)
Date received	Nov 17, 2000
Decision date	Mar 15, 2001
Days to decision	118 days
Third-party review	No
Summary / Statement	Summary
Other names	ACON THC ONE STEP MARIJUANA TEST DEVICE (URINE)

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 ...