

**K011353 ACON OPI ONE STEP OPIATES TEST STRIP, ACON
OPI ONE STEP OPIATES TEST DEVICE**Jul 30, 2001
88 days to decisionK011353 · Product code: **DJG** · Toxicology
Source: <https://www.510kdatabase.net/k011353/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Opiates (DJG)
Date received	May 3, 2001
Decision date	Jul 30, 2001
Days to decision	88 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 ...