

**K012595 ACON MTD ONE STEP METHADONE TEST STRIP AND TEST DEVICE**Oct 15, 2001  
66 days to decisionK012595 · Product code: DJR · Toxicology  
Source: <https://www.510kdatabase.net/k012595/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Methadone (DJR)
Date received	Aug 10, 2001
Decision date	Oct 15, 2001
Days to decision	66 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>ACON Laboratories, Inc.</b>
Location	San Diego, CA, US
Contact	EDWARD TUNG
Website	<a href="http://www.aconlabs.com/">http://www.aconlabs.com/</a>
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 ...