

**K093879 MISSION SALIVA ALCOHOL TEST STRIP**Aug 6, 2010  
231 days to decisionK093879 · Product code: **DIC** · Toxicology  
Source: <https://www.510kdatabase.net/k093879/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Alcohol Dehydrogenase, Specific Reagent For Ethanol Enzyme Method (DIC)
Date received	Dec 18, 2009
Decision date	Aug 6, 2010
Days to decision	231 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>ACON Laboratories, Inc.</b>
Location	San Diego, CA, US
Contact	RICHARD LENART
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 ...