

**K063295 ACON UTI URINARY TRACT INFECTION TEST STRIPS**Oct 12, 2007  
345 days to decisionK063295 · Product code: **LJX** · Chemistry  
Source: <https://www.510kdatabase.net/k063295/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Urine Leukocyte (LJX)
Date received	Nov 1, 2006
Decision date	Oct 12, 2007
Days to decision	345 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	JINN-NAN LIN
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 ...

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