

**K170587 On Call Ketone Reagent Strips for Urinalysis, Healthy Me Ketone Reagent Strips for Urinalysis**Jul 6, 2017  
128 days to decisionK170587 · Product code: JIN · Chemistry  
Source: <https://www.510kdatabase.net/k170587/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nitroprusside, Ketones (urinary, Non-quant.) (JIN)
Date received	Feb 28, 2017
Decision date	Jul 6, 2017
Days to decision	128 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	Qiyi Xie
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 ...

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k170587/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 1, 2026