

**K182384 ACR LAB Urine Analysis Test System**Jul 26, 2019  
329 days to decisionK182384 · Product code: **JFY** · Chemistry  
Source: <https://www.510kdatabase.net/k182384/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzymatic Method, Creatinine (JFY)
Date received	Aug 31, 2018
Decision date	Jul 26, 2019
Days to decision	329 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Healthy.io, Ltd.</b>
Location	Tel Aviv, IL
Contact	Ron Zohar
510(k) history	4 submissions · 4 cleared · 2018-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k182384/> 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 May 26, 2026