

**K150817 Dario Blood Glucose Monitoring System**Dec 21, 2015  
269 days to decisionK150817 · Product code: **NBW** · Chemistry  
Source: <https://www.510kdatabase.net/k150817/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Blood Glucose, Over The Counter (NBW)
Date received	Mar 27, 2015
Decision date	Dec 21, 2015
Days to decision	269 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Labstyle Innovations, Ltd.</b>
Location	Charlott, NC, US
Contact	TRACEY WIELINSKI
510(k) history	2 submissions · 2 cleared · 2015-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k150817/> 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