

**K173140 VivaChek Ino Smart Blood Glucose Monitoring System, VivaChek Ino Sync Blood Glucose Monitoring System, VivaChek Ino Sound Blood Glucose Monitoring System, VivaChek Ino Plus Blood Glucose Monitoring System, VivaChek Ino Sound Simple Blood Glucose Monitoring System, VivaChek Ino Sound Bright Blood Glucose Monitoring System**Dec 19, 2018  
446 days to decisionK173140 · Product code: **NBW** · Chemistry  
Source: <https://www.510kdatabase.net/k173140/>**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	Sep 29, 2017
Decision date	Dec 19, 2018
Days to decision	446 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Vivachek Laboratories, Inc.</b>
Location	Wilmington, DE, US
Contact	Julie Zhou
510(k) history	2 submissions · 2 cleared · 2017-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k173140/> 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 28, 2026