

**K222126 VivaChek™ Fad Blood Glucose Monitoring System,  
VivaChek™ Fad Smart Blood Glucose Monitoring System,  
VivaChek™ Fad Sync Blood Glucose Monitoring System**Aug 16, 2024  
760 days to decisionK222126 · Product code: **NBW** · Chemistry  
Source: <https://www.510kdatabase.net/k222126/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Blood Glucose, Over The Counter (NBW)
Date received	Jul 18, 2022
Decision date	Aug 16, 2024
Days to decision	760 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Vivachek Biotech (Hangzhou) Co., Ltd.</b>
Location	Hangzhou, CN
Contact	Mark Qian
510(k) history	9 submissions · 9 cleared · 2020-2025

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k222126/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 14, 2026