

K192957 VivaChek Blood Glucose and B-Ketone Monitoring System

Jun 5, 2020
228 days to decisionK192957 · Product code: JIN · Chemistry
Source: <https://www.510kdatabase.net/k192957/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nitroprusside, Ketones (urinary, Non-quant.) (JIN)
Date received	Oct 21, 2019
Decision date	Jun 5, 2020
Days to decision	228 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k192957/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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