

K193340 GoChek Blood Glucose Monitoring System, GoChek Connect Blood Glucose Monitoring SystemSep 11, 2020
284 days to decisionK193340 · Product code: **NBW** · Chemistry
Source: <https://www.510kdatabase.net/k193340/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Blood Glucose, Over The Counter (NBW)
Date received	Dec 2, 2019
Decision date	Sep 11, 2020
Days to decision	284 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Microtech Medical, Inc.
Location	Santa Clara, CA, US
Contact	Dore Mark
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	Zi-medical, Inc.
Contact	Mingzi Hussey

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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