

K231476 TRUENESS™ AIR Blood Glucose Monitoring SystemDec 1, 2023
193 days to decisionK231476 · Product code: **NBW** · Chemistry
Source: <https://www.510kdatabase.net/k231476/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Blood Glucose, Over The Counter (NBW)
Date received	May 22, 2023
Decision date	Dec 1, 2023
Days to decision	193 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	TRUENESS™ Blood Glucose Monitoring System

APPLICANT

Company	Sinocare, Inc.
Location	Changsha, CN
Contact	Qian Zhou
510(k) history	1 submissions · 1 cleared · 2023-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k231476/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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