

K182992 BGM014 Blood Glucose Monitoring SystemNov 28, 2018
30 days to decisionK182992 · Product code: **NBW** · Chemistry
Source: <https://www.510kdatabase.net/k182992/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Test, Blood Glucose, Over The Counter (NBW)
Date received	Oct 29, 2018
Decision date	Nov 28, 2018
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Apex BioTechnology Corp.
Location	Plymouth, MN, US
Contact	Lisa Liu
510(k) history	35 submissions · 35 cleared · 2001-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k182992/> Data sourced from FDA 510(k) public records (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. - Generated May 14, 2026