

K143387 GE333 Blood Glucose Monitoring SystemJun 3, 2015
189 days to decisionK143387 · Product code: **NBW** · Chemistry
Source: <https://www.510kdatabase.net/k143387/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Blood Glucose, Over The Counter (NBW)
Date received	Nov 26, 2014
Decision date	Jun 3, 2015
Days to decision	189 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bionime Coporation
Location	Mission Viejo, CA, US
Contact	Tino Lee
510(k) history	3 submissions · 3 cleared · 2014-2015

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k143387/> 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 June 4, 2026