

K123090 GLB BENEHECK PREMIUM GLU MONITORING SYSTEMNov 22, 2013
417 days to decisionK123090 · Product code: **NBW** · Chemistry
Source: <https://www.510kdatabase.net/k123090/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Blood Glucose, Over The Counter (NBW)
Date received	Oct 1, 2012
Decision date	Nov 22, 2013
Days to decision	417 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	General Life Biotechnology Co., Ltd.
Location	Mission Viejo, CA, US
Contact	Feng-Yu Lee
510(k) history	1 submissions · 1 cleared · 2013-2013

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k123090/> 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 8, 2026