

K120866 DA01 BLOOD GLUCOSE MONITORING SYSTEMDec 11, 2012
264 days to decisionK120866 · Product code: **NBW** · Chemistry
Source: <https://www.510kdatabase.net/k120866/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Blood Glucose, Over The Counter (NBW)
Date received	Mar 22, 2012
Decision date	Dec 11, 2012
Days to decision	264 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Delbio Incorporation
Location	Taoyuan, TW
Contact	NICKY PAN
510(k) history	7 submissions · 7 cleared · 2011-2014

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k120866/> 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 24, 2026