

**K100806 DIACHECK BLOOD GLUCOSE MONITORING SYSTEM
MODEL: PREMIUM**

Sep 16, 2011
543 days to decision

K100806 · Product code: **NBW** · Chemistry
Source: <https://www.510kdatabase.net/k100806/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Blood Glucose, Over The Counter (NBW)
Date received	Mar 22, 2010
Decision date	Sep 16, 2011
Days to decision	543 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.net

Device record: <https://www.510kdatabase.net/k100806/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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