

**K122307 DIAVUE PRUDENTIAL BLOOD GLUCOSE  
MONITORING SYSTEM**Apr 5, 2013  
247 days to decisionK122307 · Product code: **NBW** · Chemistry  
Source: <https://www.510kdatabase.net/k122307/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Blood Glucose, Over The Counter (NBW)
Date received	Aug 1, 2012
Decision date	Apr 5, 2013
Days to decision	247 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Biocare Corporation</b>
Location	Taoyuan County, TW
Contact	SHUCHI CHANG
510(k) history	1 submissions · 1 cleared · 2013-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k122307/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 9, 2026