

K090332 ASSURE PRO BLOOD GLUCOSE MONITORING SYSTEM, MODEL 46001Aug 14, 2009
185 days to decisionK090332 · Product code: **NBW** · Chemistry
Source: <https://www.510kdatabase.net/k090332/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Blood Glucose, Over The Counter (NBW)
Date received	Feb 10, 2009
Decision date	Aug 14, 2009
Days to decision	185 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Arkray Factory USA, Inc.
Location	Edina, MN, US
Contact	HAMID IDRISSI
510(k) history	9 submissions · 9 cleared · 2007-2011

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k090332/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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