

K090653 POCKETCHEM EZ BLOOD GLUCOSE MONITORING SYSTEMOct 9, 2009
212 days to decisionK090653 · Product code: **NBW** · Chemistry
Source: <https://www.510kdatabase.net/k090653/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Blood Glucose, Over The Counter (NBW)
Date received	Mar 11, 2009
Decision date	Oct 9, 2009
Days to decision	212 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/k090653/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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