

**K080853 DUO-CARE BLOOD GLUCOSE AND BLOOD
PRESSURE MONITOR SYSTEM**Feb 20, 2009
331 days to decisionK080853 · Product code: **NBW** · Chemistry
Source: <https://www.510kdatabase.net/k080853/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	System, Test, Blood Glucose, Over The Counter (NBW)
Date received	Mar 26, 2008
Decision date	Feb 20, 2009
Days to decision	331 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Genexel-Sein, Inc.
Location	Roswell, GA, US
Contact	JAY MANSOUR
510(k) history	2 submissions · 2 cleared · 2007-2009

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k080853/> 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 June 23, 2026