

K100398 SMARTLINK GOLD BLOOD GLUCOSE MONITORING SYSTEMJun 9, 2010
113 days to decisionK100398 · Product code: **NBW** · Chemistry
Source: <https://www.510kdatabase.net/k100398/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Test, Blood Glucose, Over The Counter (NBW)
Date received	Feb 16, 2010
Decision date	Jun 9, 2010
Days to decision	113 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Standard Diagnostics, Inc.
Location	Sound Beach, NY, US
Contact	SUSAN GOLDSTEIN-FALK
510(k) history	3 submissions · 3 cleared · 2003-2010

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