

K120558 ONETOUCH REVEAL DIABETES MANAGEMENT APPLICATIONFeb 7, 2013
349 days to decisionK120558 · Product code: **NBW** · Chemistry
Source: <https://www.510kdatabase.net/k120558/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Blood Glucose, Over The Counter (NBW)
Date received	Feb 24, 2012
Decision date	Feb 7, 2013
Days to decision	349 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Lifescan, Inc.
Location	Mchenry, IL, US
Contact	ANDREA TASKER
510(k) history	42 submissions · 42 cleared · 1981-2013

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k120558/> 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 7, 2026