

K140068 CARDIOCHEK PLUS TEST SYSTEM, CARDIOCHEK HOME TEST SYSTEMMay 22, 2015
494 days to decisionK140068 · Product code: **NBW** · Chemistry
Source: <https://www.510kdatabase.net/k140068/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Test, Blood Glucose, Over The Counter (NBW)
Date received	Jan 13, 2014
Decision date	May 22, 2015
Days to decision	494 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Polymer Technology Systems, Inc.
Location	Indianapolis, IN, US
Contact	MARGO ENRIGHT
510(k) history	27 submissions · 27 cleared · 1998-2016

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k140068/> 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 2, 2026