

K151530 CardioChek Plus Test SystemJul 7, 2015
29 days to decisionK151530 · Product code: **CGA** · Chemistry
Source: <https://www.510kdatabase.net/k151530/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Glucose Oxidase, Glucose (CGA)
Date received	Jun 8, 2015
Decision date	Jul 7, 2015
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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