

K162282 CardioChek Plus Test System, CardioChek Home Test System

Dec 22, 2016
129 days to decisionK162282 · Product code: **CGA** · Chemistry
Source: <https://www.510kdatabase.net/k162282/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Glucose Oxidase, Glucose (CGA)
Date received	Aug 15, 2016
Decision date	Dec 22, 2016
Days to decision	129 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Polymer Technology Systems, Inc. D/B/A Pts Diagnostics
Location	Indianapolis, IN, US
Contact	Margo Enright
510(k) history	3 submissions · 2 cleared · 2016-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k162282/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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