FDA 510(k) Premarket Notification

K162282 CardioChek Plus Test System, CardioChek Home Test System

CLEARED

Dec 22, 2016
129 days to decision

K162282 · 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