

K182781 PTS Professional Chemistry KitDec 21, 2018
81 days to decisionK182781 · Product code: **CGA** · Chemistry
Source: <https://www.510kdatabase.net/k182781/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - K
Submission type	Traditional
Device classification	Glucose Oxidase, Glucose (CGA)
Date received	Oct 1, 2018
Decision date	Dec 21, 2018
Days to decision	81 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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