

K193406 CardioChek Plus Test SystemFeb 26, 2022
810 days to decisionK193406 · Product code: **NBW** · Chemistry
Source: <https://www.510kdatabase.net/k193406/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Blood Glucose, Over The Counter (NBW)
Date received	Dec 9, 2019
Decision date	Feb 26, 2022
Days to decision	810 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	CardioChek Plus Home Test System

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

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