

K151545 CardioChek Plus Test System, CardioChek Home Test System, CardioChek PA Test System, CardioChek PA Home Test SystemDec 22, 2016
562 days to decisionK151545 · Product code: **CHH** · Chemistry
Source: <https://www.510kdatabase.net/k151545/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzymatic Esterase--oxidase, Cholesterol (CHH)
Date received	Jun 9, 2015
Decision date	Dec 22, 2016
Days to decision	562 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k151545/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 2, 2026