

K173952 Universal SmartECGAug 28, 2018
244 days to decisionK173952 · Product code: **DPS** · CardiovascularSource: <https://www.510kdatabase.net/k173952/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph (DPS)
Date received	Dec 27, 2017
Decision date	Aug 28, 2018
Days to decision	244 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Vectracor, Inc.
Location	Totowa, NJ, US
Contact	Andrew Schreck
510(k) history	3 submissions · 3 cleared · 2011-2018

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k173952/> 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 28, 2026