

**K160746 CARDIOLINE touchECG**Nov 2, 2016  
229 days to decisionK160746 · Product code: **DPS** · Cardiovascular  
Source: <https://www.510kdatabase.net/k160746/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph (DPS)
Date received	Mar 18, 2016
Decision date	Nov 2, 2016
Days to decision	229 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Cardioline S.P.A</b>
Location	Cavareno, TN, US
Contact	Emanuele Ercoli
510(k) history	4 submissions · 4 cleared · 2015-2023

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k160746/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 27, 2026