

K160840 ECG100+, ECG200+Aug 12, 2016
137 days to decisionK160840 · Product code: **DPS** · Cardiovascular
Source: <https://www.510kdatabase.net/k160840/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph (DPS)
Date received	Mar 28, 2016
Decision date	Aug 12, 2016
Days to decision	137 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cardioline S.P.A
Location	Cavareno, TN, US
Contact	EMANUELE ERCOLI
510(k) history	4 submissions · 4 cleared · 2015-2023

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