

**K101660 ECG SINGLE PATIENT USE LEAD WIRE SET, MODELS
2048801-5 TO 2048801-8**Aug 11, 2010
58 days to decisionK101660 · Product code: **DSA** · Cardiovascular
Source: <https://www.510kdatabase.net/k101660/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cable, Transducer And Electrode, Patient, (including Connector) (DSA)
Date received	Jun 14, 2010
Decision date	Aug 11, 2010
Days to decision	58 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Kepler Medtec
Location	Ashland, MA, US
Contact	F. DAVID ROTHKOPF
510(k) history	2 submissions · 2 cleared · 2010-2011

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