

K050443 ACCU-LEADSep 2, 2005
192 days to decisionK050443 · Product code: **DRX** · Cardiovascular
Source: <https://www.510kdatabase.net/k050443/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Electrocardiograph (DRX)
Date received	Feb 22, 2005
Decision date	Sep 2, 2005
Days to decision	192 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Kentec Medical, Inc.
Location	Irvine, CA, US
Contact	DAVID SHERATON
510(k) history	6 submissions · 6 cleared · 1985-2012

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