FDA 510(k) Premarket Notification

K050443 ACCU-LEAD

CLEARED

Sep 2, 2005
192 days to decision

K050443 · 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