FDA 510(k) Premarket Notification

K043361 ACCUHEART ELECTRODE BELT

CLEARED

Mar 22, 2005
105 days to decision

K043361 · Product code: **DRX** · Cardiovascular
Source: https://www.510kdatabase.net/k043361/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Electrocardiograph (DRX)
Date received	Dec 7, 2004
Decision date	Mar 22, 2005
Days to decision	105 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Advanced Bioelectric Corporation**
Location	Montreal, Qc, CA
Contact	MARC-ANDRE COTE
510(k) history	1 submissions · 1 cleared · 2005-2005