

**K853038 DE12 RAPID TRACE AT-REST DIAGNOSTIC ECG ELECTRODES**Jan 7, 1986  
172 days to decisionK853038 · Product code: **DRX** · Cardiovascular  
Source: <https://www.510kdatabase.net/k853038/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Electrocardiograph (DRX)
Date received	Jul 19, 1985
Decision date	Jan 7, 1986
Days to decision	172 days
Third-party review	No

**APPLICANT**

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Company	<b>Bio-Detek, Inc.</b>
Location	Mansfield, MA, US
Contact	DONALD C EPSTEIN
510(k) history	17 submissions · 17 cleared · 1985-2015

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k853038/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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