

K964213 TRACE RITE SOLID GEL ECG ELECTRODESNov 25, 1996
34 days to decisionK964213 · Product code: **DRX** · CardiovascularSource: <https://www.510kdatabase.net/k964213/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Electrocardiograph (DRX)
Date received	Oct 22, 1996
Decision date	Nov 25, 1996
Days to decision	34 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Bio-Detek, Inc.
Location	Mansfield, MA, US
Contact	MICHAEL R DUPELLE
510(k) history	17 submissions · 17 cleared · 1985-2015

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