

K912714 RT40 RADIO TRANSLUCENTJul 25, 1991
37 days to decisionK912714 · Product code: **DRX** · Cardiovascular
Source: <https://www.510kdatabase.net/k912714/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Electrocardiograph (DRX)
Date received	Jun 18, 1991
Decision date	Jul 25, 1991
Days to decision	37 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Bio-Detek, Inc.
Location	Mansfield, MA, US
Contact	ROBERT E SIMMONS
510(k) history	17 submissions · 17 cleared · 1985-2015

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