

K921164 MODEL 1300 SOFTRACE II ELECTRODEMar 18, 1993
372 days to decisionK921164 · Product code: **DRX** · CardiovascularSource: <https://www.510kdatabase.net/k921164/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Electrocardiograph (DRX)
Date received	Mar 11, 1992
Decision date	Mar 18, 1993
Days to decision	372 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Medtronic Vascular
Location	Walker, MI, US
Contact	JANICE M PEVIDE
510(k) history	475 submissions · 453 cleared · 1977-2023

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