FDA 510(k) Premarket Notification

K910494 RESTING EKG ELECTRODE SERIES

CLEARED

Apr 22, 1991
76 days to decision

K910494 · Product code: **DRX** · Cardiovascular
Source: https://www.510kdatabase.net/k910494/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Electrocardiograph (DRX)
Date received	Feb 5, 1991
Decision date	Apr 22, 1991
Days to decision	76 days
Third-party review	No

APPLICANT

Company	**Medtronic Andover Medical, Inc.**
Location	Lowell, MA, US
Contact	JANICE M PEVIDE
510(k) history	6 submissions · 6 cleared · 1985-1991