FDA 510(k) Premarket Notification

K875041 FOAM BORDERED DIAGNOSTIC (CARE) ELECTRODE

CLEARED

Jan 28, 1988
56 days to decision

K875041 · Product code: **DRX** · Cardiovascular
Source: https://www.510kdatabase.net/k875041/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Electrocardiograph (DRX)
Date received	Dec 3, 1987
Decision date	Jan 28, 1988
Days to decision	56 days
Third-party review	No

APPLICANT

Company	**Labeltape Meditect, Inc.**
Location	Grand Rapids, MI, US
Contact	MICHAEL S BARTLETT
510(k) history	26 submissions · 26 cleared · 1986-1995