FDA 510(k) Premarket Notification

K853993 DOBE (MODIFIED)

CLEARED

Feb 28, 1986
154 days to decision

K853993 · Product code: **DRX** · Cardiovascular
Source: https://www.510kdatabase.net/k853993/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Electrocardiograph (DRX)
Date received	Sep 27, 1985
Decision date	Feb 28, 1986
Days to decision	154 days
Third-party review	No

APPLICANT

Company	**Phoenix Medical Technology, Inc.**
Location	Andrews, SC, US
Contact	SAUVE
510(k) history	11 submissions · 11 cleared · 1986-2000