FDA 510(k) Premarket Notification

K893425 VITATRACE

CLEARED

Jul 14, 1989
73 days to decision

K893425 · Product code: **DRX** · Cardiovascular
Source: https://www.510kdatabase.net/k893425/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Electrocardiograph (DRX)
Date received	May 2, 1989
Decision date	Jul 14, 1989
Days to decision	73 days
Third-party review	No

APPLICANT

Company	**Lectec Corp.**
Location	Mchenry, IL, US
Contact	DAVID MONTECALVO
510(k) history	27 submissions · 26 cleared · 1977-1996