FDA 510(k) Premarket Notification

K010396 C. NET 2100

CLEARED

Oct 4, 2001
237 days to decision

K010396 · Product code: **MLO** · Cardiovascular
Source: https://www.510kdatabase.net/k010396/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph, Ambulatory, With Analysis Algorithm (MLO)
Date received	Feb 9, 2001
Decision date	Oct 4, 2001
Days to decision	237 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Cardionetics, Ltd.**
Location	Waltham, MA, US
Contact	BARRY SALL
510(k) history	1 submissions · 1 cleared · 2001-2001