FDA 510(k) Premarket Notification

K972121 ACUITY CENTRAL STATION

CLEARED

Nov 7, 1997
155 days to decision

K972121 · Product code: **MLD** · Cardiovascular
Source: https://www.510kdatabase.net/k972121/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, St Segment With Alarm (MLD)
Date received	Jun 5, 1997
Decision date	Nov 7, 1997
Days to decision	155 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Protocol Systems, Inc.**
Location	Beaverton, OR, US
Contact	JAMES P WELCH
510(k) history	15 submissions · 14 cleared · 1988-2000