

**K972121 ACUITY CENTRAL STATION**Nov 7, 1997  
155 days to decisionK972121 · 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	<b>Protocol Systems, Inc.</b>
Location	Beaverton, OR, US
Contact	JAMES P WELCH
510(k) history	15 submissions · 14 cleared · 1988-2000

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k972121/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 26, 2026