

**K042463 HOLTER PLUS**Sep 22, 2004  
9 days to decisionK042463 · Product code: **DQK** · CardiovascularSource: <https://www.510kdatabase.net/k042463/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Sep 13, 2004
Decision date	Sep 22, 2004
Days to decision	9 days
Third-party review	Yes
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Rozinn Electronics, Inc.</b>
Location	Glendale, NY, US
Contact	MARK ROSOFF
510(k) history	6 submissions · 6 cleared · 1990-2006

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k042463/> 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 June 28, 2026