

**K963375 CARDIACMONITOR**Feb 28, 1997  
185 days to decisionK963375 · Product code: **DXH** · CardiovascularSource: <https://www.510kdatabase.net/k963375/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transmitters And Receivers, Electrocardiograph, Telephone (DXH)
Date received	Aug 27, 1996
Decision date	Feb 28, 1997
Days to decision	185 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Vision Electronics</b>
Location	Kirkwood, NY, US
Contact	SHAWN P WOOD
510(k) history	2 submissions · 2 cleared · 1997-1997

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k963375/> 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 July 4, 2026