

**K914105 CATHWRITER(TM)**Feb 26, 1992  
166 days to decisionK914105 · Product code: **DQK** · Cardiovascular  
Source: <https://www.510kdatabase.net/k914105/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Sep 13, 1991
Decision date	Feb 26, 1992
Days to decision	166 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Softheart, Inc.</b>
Location	South Burlington, VT, US
Contact	HENRY A GELLER
510(k) history	3 submissions · 3 cleared · 1992-1993

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k914105/> 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 6, 2026