

**K984058 ACIST INJECTOR SYSTEM, MODEL CL100 H**Feb 11, 1999  
90 days to decisionK984058 · Product code: **IZQ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k984058/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Injector, Contrast Medium, Automatic (IZQ)
Date received	Nov 13, 1998
Decision date	Feb 11, 1999
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Acist Medical Systems</b>
Location	Eden Prairie, MN, US
Contact	KATE ANDERSON
510(k) history	7 submissions · 7 cleared · 1999-2014

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k984058/> 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 7, 2026