

**K991103 MODIFICATION TO ACIST CL 100H**May 31, 2000  
426 days to decisionK991103 · Product code: **DXT** · Cardiovascular  
Source: <https://www.510kdatabase.net/k991103/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Injector And Syringe, Angiographic (DXT)
Date received	Apr 1, 1999
Decision date	May 31, 2000
Days to decision	426 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	CARL M BEAURLINE
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/k991103/> 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