

K020892 ACIST GENTOO CONTRAST INJECTION SYSTEMJan 27, 2003
314 days to decisionK020892 · Product code: **DXT** · Cardiovascular
Source: <https://www.510kdatabase.net/k020892/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Injector And Syringe, Angiographic (DXT)
Date received	Mar 19, 2002
Decision date	Jan 27, 2003
Days to decision	314 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Acist Medical Systems
Location	Eden Prairie, MN, US
Contact	CARL M BEAURLINE
510(k) history	7 submissions · 7 cleared · 1999-2014

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k020892/> Data sourced from FDA 510(k) public records (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. - Generated June 7, 2026