

**K021015 ACIST PLUS 4 ANGIOGRAPHIC CATHETER**Apr 26, 2002  
28 days to decisionK021015 · Product code: **DQO** · CardiovascularSource: <https://www.510kdatabase.net/k021015/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)        |
| Submission type       | Special                                   |
| Device classification | Catheter, Intravascular, Diagnostic (DQO) |
| Date received         | Mar 29, 2002                              |
| Decision date         | Apr 26, 2002                              |
| Days to decision      | 28 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/k021015/> 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