

K953987 ACS TOURGIDE GUIDING CATHETERDec 7, 1995
106 days to decisionK953987 · Product code: **DQY** · Cardiovascular
Source: <https://www.510kdatabase.net/k953987/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Catheter, Percutaneous (DQY) |
| Date received | Aug 23, 1995 |
| Decision date | Dec 7, 1995 |
| Days to decision | 106 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | Advanced Cardiovascular Systems, Inc. |
| Location | Santa Clara, CA, US |
| Contact | MARIANNE C DRENNAN |
| 510(k) history | 103 submissions · 100 cleared · 1982-2002 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k953987/> 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 July 1, 2026