

K942066 ACS HI-TORQUE EXTRA S'PORT GUIDE WIREJul 18, 1994
80 days to decisionK942066 · Product code: **DQX** · Cardiovascular
Source: <https://www.510kdatabase.net/k942066/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Wire, Guide, Catheter (DQX) |
| Date received | Apr 29, 1994 |
| Decision date | Jul 18, 1994 |
| Days to decision | 80 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k942066/> 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