

K970823 SCIMED 8 FRENCH WISEGUIDE GUIDE CATHETERJun 3, 1997
89 days to decisionK970823 · Product code: **DQY** · Cardiovascular
Source: <https://www.510kdatabase.net/k970823/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Catheter, Percutaneous (DQY) |
| Date received | Mar 6, 1997 |
| Decision date | Jun 3, 1997 |
| Days to decision | 89 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Scimed Life Systems, Inc. |
| Location | Mchenry, IL, US |
| Contact | ANGELA RUAN |
| 510(k) history | 109 submissions · 108 cleared · 1977-1998 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k970823/> 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 29, 2026