

**K850829 WIRE, GUIDE, CATHETER**Jun 26, 1985  
121 days to decisionK850829 · Product code: **DQY** · CardiovascularSource: <https://www.510kdatabase.net/k850829/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Catheter, Percutaneous (DQY)       |
| Date received         | Feb 25, 1985                       |
| Decision date         | Jun 26, 1985                       |
| Days to decision      | 121 days                           |
| Third-party review    | No                                 |

**APPLICANT**

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|----------------|---|
| Company        | <b>Lake Region Mfg., Inc.</b>           |
| Location       | Mchenry, IL, US                         |
| Contact        | JIM KLOSTERMAN                          |
| 510(k) history | 42 submissions · 42 cleared · 1977-2010 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k850829/> 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 May 22, 2026