

**K912878 OPEN ENDED GUIDEWIRE**Sep 11, 1991  
72 days to decisionK912878 · Product code: **DQX** · CardiovascularSource: <https://www.510kdatabase.net/k912878/>**SUBMISSION DETAILS**

---

|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Wire, Guide, Catheter (DQX)        |
| Date received         | Jul 1, 1991                        |
| Decision date         | Sep 11, 1991                       |
| Days to decision      | 72 days                            |
| Third-party review    | No                                 |
| Summary / Statement   | Statement                          |

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k912878/> 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