FDA 510(k) Premarket Notification

# K242824 PTFE Guidewire

**CLEARED**

Dec 6, 2024
79 days to decision

K242824 · Product code: **DQX** · Cardiovascular
Source: https://www.510kdatabase.net/k242824/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Wire, Guide, Catheter (DQX) |
| Date received | Sep 18, 2024 |
| Decision date | Dec 6, 2024 |
| Days to decision | 79 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Lake Region Medical** |
| Location | Chaska, MN, US |
| Contact | Clara Lee |
| 510(k) history | 16 submissions · 16 cleared · 2008-2026 |