FDA 510(k) Premarket Notification

# K254137 InQwire Amplatz Guide Wire

**CLEARED**

May 22, 2026
151 days to decision

K254137 · Product code: **DQX** · Cardiovascular
Source: https://www.510kdatabase.net/k254137/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Wire, Guide, Catheter (DQX) |
| Date received | Dec 22, 2025 |
| Decision date | May 22, 2026 |
| Days to decision | 151 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Merit Medical Ireland, Ltd.** |
| Location | South Jordan, UT, US |
| Contact | Brian Coughlan |
| 510(k) history | 5 submissions · 5 cleared · 2012-2026 |