FDA 510(k) Premarket Notification

# K080364 FINDRWIRZ GUIDE WIRE SYSTEM

**CLEARED**

Aug 11, 2008
182 days to decision

K080364 · Product code: **DQX** · Cardiovascular
Source: https://www.510kdatabase.net/k080364/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Wire, Guide, Catheter (DQX) |
| Date received | Feb 11, 2008 |
| Decision date | Aug 11, 2008 |
| Days to decision | 182 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Sentreheart, Inc.** |
| Location | Palo Alto, CA, US |
| Contact | LINDA GUTHRIE |
| 510(k) history | 5 submissions · 5 cleared · 2008-2015 |

**510k Database** - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k080364/ 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 3, 2026