FDA 510(k) Premarket Notification

# K120119 SUNMED GUIDE WIRE

**CLEARED**

May 11, 2012
115 days to decision

K120119 · Product code: **DQX** · Cardiovascular
Source: https://www.510kdatabase.net/k120119/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Wire, Guide, Catheter (DQX) |
| Date received | Jan 17, 2012 |
| Decision date | May 11, 2012 |
| Days to decision | 115 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Sunny Medical Device (Shenzhen) Co., Ltd.** |
| Location | Irvine, CA, US |
| Contact | GREG HOLLAND |
| 510(k) history | 6 submissions · 6 cleared · 2012-2020 |