FDA 510(k) Premarket Notification

# K991646 AGILITY STEERABLE GUIDEWIRE

**CLEARED**

Sep 23, 1999
133 days to decision

K991646 · Product code: **DQX** · Cardiovascular
Source: https://www.510kdatabase.net/k991646/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Wire, Guide, Catheter (DQX) |
| Date received | May 13, 1999 |
| Decision date | Sep 23, 1999 |
| Days to decision | 133 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Cordis Neurovascular, Inc.** |
| Location | Miami Lakes, FL, US |
| Contact | MARITZA CELAYA |
| 510(k) history | 37 submissions · 37 cleared · 1994-2008 |