FDA 510(k) Premarket Notification

# K111010 SPIDERFX EMBOLIC PROTECTION DEVICE

**CLEARED**

Oct 27, 2011
199 days to decision

K111010 · Product code: **NTE** · Cardiovascular
Source: https://www.510kdatabase.net/k111010/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Temporary Carotid Catheter For Embolic Capture (NTE) |
| Date received | Apr 11, 2011 |
| Decision date | Oct 27, 2011 |
| Days to decision | 199 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Ev3, Inc.** |
| Location | Plymouth, MN, US |
| Contact | BRENDA JOHNSON |
| 510(k) history | 35 submissions · 26 cleared · 2003-2014 |