

K063785 SPIDERFX EMBOLIC PROTECTION DEVICEJan 19, 2007
29 days to decisionK063785 · Product code: **NFA** · Cardiovascular
Source: <https://www.510kdatabase.net/k063785/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Temporary Coronary Saphenous Vein Bypass Graft For Embolic Protection (NFA) |
| Date received | Dec 21, 2006 |
| Decision date | Jan 19, 2007 |
| Days to decision | 29 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

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

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