

K052166 MODIFICATION TO: RX ACCUNET EMBOLIC PROTECTION SYSTEMAug 18, 2005
9 days to decisionK052166 · Product code: NTE · Cardiovascular
Source: <https://www.510kdatabase.net/k052166/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Temporary Carotid Catheter For Embolic Capture (NTE) |
| Date received | Aug 9, 2005 |
| Decision date | Aug 18, 2005 |
| Days to decision | 9 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Guidant Corporation |
| Location | St. Paul, MN, US |
| Contact | JULIA ANASTAS |
| 510(k) history | 15 submissions · 12 cleared · 2003-2006 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k052166/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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