

K113428 ANGIOJET ULTRA DVX THROMBECTOMY SETDec 2, 2011
11 days to decisionK113428 · Product code: **QEZ** · Cardiovascular
Source: <https://www.510kdatabase.net/k113428/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Aspiration Thrombectomy Catheter (QEZ) |
| Date received | Nov 21, 2011 |
| Decision date | Dec 2, 2011 |
| Days to decision | 11 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Medrad, Inc. |
| Location | Mchenry, IL, US |
| Contact | MIKE BURNSIDE |
| Website | http://www.medrad.com/ |
| 510(k) history | 105 submissions · 105 cleared · 1976-2014 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k113428/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 17, 2026