

K113757 ASPIRE MAX ASPIRATION CATHETERFeb 22, 2012
63 days to decisionK113757 · Product code: **QEZ** · Cardiovascular
Source: <https://www.510kdatabase.net/k113757/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Aspiration Thrombectomy Catheter (QEZ) |
| Date received | Dec 21, 2011 |
| Decision date | Feb 22, 2012 |
| Days to decision | 63 days |
| Third-party review | Yes |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | Control Medical Technology, LLC |
| Location | Park City, UT, US |
| Contact | SHAWN P FOJTIK |
| 510(k) history | 2 submissions · 2 cleared · 2012-2013 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k113757/> 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 June 8, 2026