

**K070403 PRONTO .035 EXTRACTION CATHETER**Jun 13, 2007  
121 days to decisionK070403 · Product code: **QEZ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k070403/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)     |
| Submission type       | Traditional                            |
| Device classification | Aspiration Thrombectomy Catheter (QEZ) |
| Date received         | Feb 12, 2007                           |
| Decision date         | Jun 13, 2007                           |
| Days to decision      | 121 days                               |
| Third-party review    | No                                     |
| Summary / Statement   | Summary                                |

**APPLICANT**

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|----------------|---|
| Company        | <b>Vascular Solutions, Inc.</b>                 |
| Location       | Minneapolis, MN, US                             |
| Contact        | DORALIE POGANSKI                                |
| Website        | <a href="http://vasc.com/">http://vasc.com/</a> |
| 510(k) history | 103 submissions · 102 cleared · 2002-2018       |

Vascular Solutions, Inc. specialized in cardiovascular interventional devices with a manufacturing facility in Minneapolis, US. The company developed a broad portfolio of catheters, guidewires, and vascular access systems for interventional cardiology and radiology procedures. The company received FDA 510(k) clearances from total submissions between 2002 and 2018. All submissions in the regulatory record were cleared. Cardiovascular devices dominated the company's portfolio, including mechanical thrombectomy systems, aspiration systems, guidewires, and vascular closure te...

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