

**K052258 VASCULAR SOLUTIONS SKYWAY SUPPORT  
CATHETER**Dec 13, 2005  
116 days to decisionK052258 · Product code: **DQY** · Cardiovascular  
Source: <https://www.510kdatabase.net/k052258/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Catheter, Percutaneous (DQY)       |
| Date received         | Aug 19, 2005                       |
| Decision date         | Dec 13, 2005                       |
| Days to decision      | 116 days                           |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---|
| Company        | <b>Vascular Solutions, Inc.</b>                 |
| Location       | Minneapolis, MN, US                             |
| Contact        | SARA L COON                                     |
| 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...