

K091304 VORTEX CANNULAJul 2, 2009
59 days to decisionK091304 · Product code: **DWF** · Cardiovascular
Source: <https://www.510kdatabase.net/k091304/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass (DWF) |
| Date received | May 4, 2009 |
| Decision date | Jul 2, 2009 |
| Days to decision | 59 days |
| Third-party review | Yes |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Vortex Medical, Inc. |
| Location | Norwell, MA, US |
| Contact | CHERYL BLAKE |
| 510(k) history | 3 submissions · 3 cleared · 2009-2014 |

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