

**K092486 VORTEX MEDICAL ANGIOVAC CARDIOPULMONARY
BYPASS CIRCUIT**Aug 28, 2009
15 days to decisionK092486 · Product code: **DWE** · Cardiovascular
Source: <https://www.510kdatabase.net/k092486/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tubing, Pump, Cardiopulmonary Bypass (DWE)
Date received	Aug 13, 2009
Decision date	Aug 28, 2009
Days to decision	15 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k092486/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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