

K191557 CentriMag Acute Circulatory Support SystemJul 10, 2019
28 days to decisionK191557 · Product code: **DWA** · CardiovascularSource: <https://www.510kdatabase.net/k191557/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Control, Pump Speed, Cardiopulmonary Bypass (DWA)
Date received	Jun 12, 2019
Decision date	Jul 10, 2019
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Thoratec Corporation (Now Part of Abbott)
Location	Pleasanton, CA, US
Contact	Lori Dondiego
510(k) history	1 submissions · 1 cleared · 2019-2019

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