

K202751 TandemHeart Pump and Escort ControllerMar 26, 2021
186 days to decisionK202751 · Product code: **QNR** · CardiovascularSource: <https://www.510kdatabase.net/k202751/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Blood Pump For Ecmo, Long-term (> 6 Hours) Use (QNR)
Date received	Sep 21, 2020
Decision date	Mar 26, 2021
Days to decision	186 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Cardiacassist, Inc.
Location	Pittsburgh, PA, US
Contact	Megan Walsh
510(k) history	21 submissions · 21 cleared · 2000-2024

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