

K232480 ProtekDuo Veno-Venous Cannula SetsOct 6, 2023
51 days to decisionK232480 · Product code: **PZS** · Cardiovascular
Source: <https://www.510kdatabase.net/k232480/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dual Lumen Ecmo Cannula (PZS)
Date received	Aug 16, 2023
Decision date	Oct 6, 2023
Days to decision	51 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k232480/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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