

K153295 TandemLung OxygenatorFeb 26, 2016
105 days to decisionK153295 · Product code: **DTZ** · Cardiovascular
Source: <https://www.510kdatabase.net/k153295/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Nov 13, 2015
Decision date	Feb 26, 2016
Days to decision	105 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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