

K222535 OCS Lung Donor Flush SetNov 18, 2022
88 days to decisionK222535 · Product code: **MSB** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k222535/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System And Accessories, Isolated Heart, Transport And Preservation (MSB)
Date received	Aug 22, 2022
Decision date	Nov 18, 2022
Days to decision	88 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	TransMedics, Inc.
Location	Andover, MA, US
Contact	Miriam Provost
510(k) history	3 submissions · 3 cleared · 2021-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k222535/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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