

K211314 OCS Lung SolutionJul 29, 2021
90 days to decisionK211314 · Product code: **MSB** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k211314/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System And Accessories, Isolated Heart, Transport And Preservation (MSB)
Date received	Apr 30, 2021
Decision date	Jul 29, 2021
Days to decision	90 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

REGULATORY CONSULTANT

Consulting firm	Biologics Consulting Group, Inc.
Contact	Christy Foreman

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k211314/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 25, 2026