

K221373 Essenz HLMMar 9, 2023
301 days to decisionK221373 · Product code: **DTQ** · CardiovascularSource: <https://www.510kdatabase.net/k221373/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Console, Heart-lung Machine, Cardiopulmonary Bypass (DTQ)
Date received	May 12, 2022
Decision date	Mar 9, 2023
Days to decision	301 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Livanova Deutschland, GmbH
Location	Munich, DE
Contact	Julia E. Leslie
510(k) history	7 submissions · 7 cleared · 2020-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k221373/> 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 24, 2026