

**K232291 Essenz HLM, Essenz ILBM**Aug 24, 2023  
23 days to decisionK232291 · Product code: **DTQ** · CardiovascularSource: <https://www.510kdatabase.net/k232291/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Console, Heart-lung Machine, Cardiopulmonary Bypass (DTQ)
Date received	Aug 1, 2023
Decision date	Aug 24, 2023
Days to decision	23 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Livanova Deutschland, GmbH</b>
Location	Munich, DE
Contact	Florian Goetz
510(k) history	7 submissions · 7 cleared · 2020-2023

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k232291/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 24, 2026