

**K220635 Heater-Cooler System 3T**Nov 16, 2022  
257 days to decisionK220635 · Product code: **DWC** · CardiovascularSource: <https://www.510kdatabase.net/k220635/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Controller, Temperature, Cardiopulmonary Bypass (DWC)
Date received	Mar 4, 2022
Decision date	Nov 16, 2022
Days to decision	257 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k220635/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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