

K191402 Heater-Cooler System 3TFeb 25, 2020
277 days to decisionK191402 · Product code: **DWC** · Cardiovascular
Source: <https://www.510kdatabase.net/k191402/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Controller, Temperature, Cardiopulmonary Bypass (DWC)
Date received	May 24, 2019
Decision date	Feb 25, 2020
Days to decision	277 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Livanova Deutschland, GmbH
Location	Munich, DE
Contact	Scott Light
510(k) history	7 submissions · 7 cleared · 2020-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k191402/> 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