

**K202154 B-Capta**Apr 1, 2021  
241 days to decisionK202154 · Product code: **DRY** · CardiovascularSource: <https://www.510kdatabase.net/k202154/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Blood-gas, On-line, Cardiopulmonary Bypass (DRY)
Date received	Aug 3, 2020
Decision date	Apr 1, 2021
Days to decision	241 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k202154/> 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