FDA 510(k) Premarket Notification

K232291 Essenz HLM, Essenz ILBM

CLEARED

Aug 24, 2023
23 days to decision

K232291 · Product code: **DTQ** · Cardiovascular
Source: 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	**Livanova Deutschland, GmbH**
Location	Munich, DE
Contact	Florian Goetz
510(k) history	7 submissions · 7 cleared · 2020-2023