FDA 510(k) Premarket Notification

K221373 Essenz HLM

CLEARED

Mar 9, 2023
301 days to decision

K221373 · Product code: **DTQ** · Cardiovascular
Source: https://www.510kdatabase.net/k221373/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Console, Heart-lung Machine, Cardiopulmonary Bypass (DTQ)
Date received	May 12, 2022
Decision date	Mar 9, 2023
Days to decision	301 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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