FDA 510(k) Premarket Notification

K210130 Stockert S5 System

CLEARED

Apr 5, 2021
76 days to decision

K210130 · Product code: **DTQ** · Cardiovascular
Source: https://www.510kdatabase.net/k210130/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Console, Heart-lung Machine, Cardiopulmonary Bypass (DTQ)
Date received	Jan 19, 2021
Decision date	Apr 5, 2021
Days to decision	76 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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