FDA 510(k) Premarket Notification

K212003 ESSENZ Patient Monitor

CLEARED

Nov 10, 2021
135 days to decision

K212003 · Product code: **DXJ** · Cardiovascular
Source: https://www.510kdatabase.net/k212003/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Display, Cathode-ray Tube, Medical (DXJ)
Date received	Jun 28, 2021
Decision date	Nov 10, 2021
Days to decision	135 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