

**K212003 ESSENZ Patient Monitor**Nov 10, 2021  
135 days to decisionK212003 · Product code: **DXJ** · CardiovascularSource: <https://www.510kdatabase.net/k212003/>**SUBMISSION DETAILS**

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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**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212003/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 24, 2026