

K191273 Multi-Link X2 ECG and SpO2 AdapterSep 13, 2019
123 days to decisionK191273 · Product code: **DSA** · Cardiovascular
Source: <https://www.510kdatabase.net/k191273/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cable, Transducer And Electrode, Patient, (including Connector) (DSA)
Date received	May 13, 2019
Decision date	Sep 13, 2019
Days to decision	123 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Vyair Medical, Inc.
Location	Helsinki, FI
Contact	Suzanne Moreno
510(k) history	9 submissions · 9 cleared · 2018-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k191273/> Data sourced from FDA 510(k) public records (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. - Generated May 24, 2026