

K211294 Multi-Link X2 ECG Cable and Leadwire SystemAug 16, 2021
110 days to decisionK211294 · Product code: **DSA** · CardiovascularSource: <https://www.510kdatabase.net/k211294/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cable, Transducer And Electrode, Patient, (including Connector) (DSA)
Date received	Apr 28, 2021
Decision date	Aug 16, 2021
Days to decision	110 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k211294/> 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