

K221901 EleGARDJul 29, 2022
29 days to decisionK221901 · Product code: **FOA** · General Hospital
Source: <https://www.510kdatabase.net/k221901/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Board, Cardiopulmonary (FOA)
Date received	Jun 30, 2022
Decision date	Jul 29, 2022
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Advancedcpr Solutions, LLC
Location	Edina, MN, US
Contact	Philip Faris
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	ProMedic Consulting, LLC
Contact	Paul Dryden

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k221901/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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