

K220106 QardioArm 2Jun 15, 2022
154 days to decisionK220106 · Product code: **DXN** · Cardiovascular
Source: <https://www.510kdatabase.net/k220106/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Jan 12, 2022
Decision date	Jun 15, 2022
Days to decision	154 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Qardio, Inc.
Location	Walnut, CA, US
Contact	Rosario Iannella
510(k) history	3 submissions · 3 cleared · 2014-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k220106/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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