FDA 510(k) Premarket Notification

K220106 QardioArm 2

CLEARED

Jun 15, 2022
154 days to decision

K220106 · 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