FDA 510(k) Premarket Notification

K201644 QardioCore

CLEARED

Feb 28, 2021
256 days to decision

K201644 · Product code: **DSH** · Cardiovascular
Source: https://www.510kdatabase.net/k201644/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Recorder, Magnetic Tape, Medical (DSH)
Date received	Jun 17, 2020
Decision date	Feb 28, 2021
Days to decision	256 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