

**K201644 QardioCore**Feb 28, 2021  
256 days to decisionK201644 · Product code: **DSH** · CardiovascularSource: <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	<b>Qardio, Inc.</b>
Location	Walnut, CA, US
Contact	Rosario Iannella
510(k) history	3 submissions · 3 cleared · 2014-2022

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k201644/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 27, 2026