

K140067 QARDIOARMJun 18, 2014
159 days to decisionK140067 · Product code: **DXN** · Cardiovascular
Source: <https://www.510kdatabase.net/k140067/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Measurement, Blood-pressure, Non-invasive (DXN) |
| Date received | Jan 10, 2014 |
| Decision date | Jun 18, 2014 |
| Days to decision | 159 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Qardio, Inc. |
| Location | Walnut, CA, US |
| Contact | JEN KE-MIN |
| 510(k) history | 3 submissions · 3 cleared · 2014-2022 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k140067/> Data sourced from FDA 510(k) public records (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. - Generated May 27, 2026