

K150990 ECVUE Mapping SystemJul 2, 2015
78 days to decisionK150990 · Product code: **DQK** · Cardiovascular
Source: <https://www.510kdatabase.net/k150990/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Computer, Diagnostic, Programmable (DQK) |
| Date received | Apr 15, 2015 |
| Decision date | Jul 2, 2015 |
| Days to decision | 78 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|-----------------------------------------|
| Company | Cardioinsight Technologies, Inc. |
| Location | Cleveland, OH, US |
| Contact | Christina V Vacca |
| 510(k) history | 3 submissions · 3 cleared · 2014-2016 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k150990/> 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 June 2, 2026