

**K210543 IM007**Nov 3, 2021  
252 days to decisionK210543 · Product code: **DQK** · Cardiovascular  
Source: <https://www.510kdatabase.net/k210543/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Feb 24, 2021
Decision date	Nov 3, 2021
Days to decision	252 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Implicity, Inc.</b>
Location	Cambridge, MA, US
Contact	David Perlmutter
510(k) history	2 submissions · 2 cleared · 2021-2023

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Mj Medtech Consulting Services, LLC</b>
Contact	Mark Johnson

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

---

510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k210543/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 25, 2026