FDA 510(k) Premarket Notification

K210543 IM007

CLEARED

Nov 3, 2021
252 days to decision

K210543 · 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	**Implicity, Inc.**
Location	Cambridge, MA, US
Contact	David Perlmutter
510(k) history	2 submissions · 2 cleared · 2021-2023

REGULATORY CONSULTANT

Consulting firm	**Mj Medtech Consulting Services, LLC**
Contact	Mark Johnson

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