

K250749 PhysCade SystemJun 4, 2025
84 days to decisionK250749 · Product code: **DQK** · Cardiovascular
Source: <https://www.510kdatabase.net/k250749/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Mar 12, 2025
Decision date	Jun 4, 2025
Days to decision	84 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Physcade, Inc.
Location	Palo Alto, CA, US
Contact	Raphael Michel
Website	https://www.physcade.com/
510(k) history	1 submissions · 1 cleared · 2025-2025

Physcade, Inc. develops medical devices with a manufacturing facility in Palo Alto, US. The company specializes in Cardiovascular devices and solutions. Physcade has received FDA 510(k) clearance from total submission. The company's regulatory activity is focused entirely on Cardiovascular devices. The first and latest clearance occurred in 2025, reflecting active regulatory engagement. Explore the company's cleared device names, product codes, and clearance dates in the database.
