

K250747 Globe® Pulsed Field SystemJun 25, 2025
105 days to decisionK250747 · Product code: **DQK** · CardiovascularSource: <https://www.510kdatabase.net/k250747/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Mar 12, 2025
Decision date	Jun 25, 2025
Days to decision	105 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Kardium, Inc.
Location	Burnaby, CA
Contact	Ricardo Romero
510(k) history	2 submissions · 2 cleared · 2025-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250747/> 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 14, 2026