FDA 510(k) Premarket Notification

K250747 Globe® Pulsed Field System

CLEARED

Jun 25, 2025
105 days to decision

K250747 · Product code: **DQK** · Cardiovascular
Source: 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