FDA 510(k) Premarket Notification

K232616 Volta AF-Xplorer

CLEARED

Sep 27, 2023
30 days to decision

K232616 · Product code: **DQK** · Cardiovascular
Source: https://www.510kdatabase.net/k232616/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Aug 28, 2023
Decision date	Sep 27, 2023
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Volta Medical**
Location	Marseille, FR
Contact	Paola Milpied
510(k) history	5 submissions · 5 cleared · 2020-2025