FDA 510(k) Premarket Notification

K243812 Volta AF-Xplorer

CLEARED

May 9, 2025
149 days to decision

K243812 · Product code: **DQK** · Cardiovascular
Source: https://www.510kdatabase.net/k243812/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Dec 11, 2024
Decision date	May 9, 2025
Days to decision	149 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	**Hogan Lovells US LLP**
Contact	Kristin Duggan

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

CLINICAL EVIDENCE - NCT04702451

Tailored vs. Anatomical Ablation Strategy for Persistent Atrial Fibrillation

Status	Completed
Enrollment	377 patients (actual)
Study sites	26 sites
Condition studied	Atrial Fibrillation
Primary purpose	Treatment
Study type	Interventional
Study design	Parallel
Masking	Double blind
Completion date	Dec 27, 2023
Sponsor	Volta Medical (Industry)

Primary outcome

Number of Participants Free From Documented AF After One Ablation Procedure

Secondary outcome

Number of Participants Free From Documented AF/AT After One or Two Ablation Procedures

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT04702451