FDA 510(k) Premarket Notification

CLEARED

K211546 Vektor Computational ECG Mapping System (vMap)

Nov 9, 2021
174 days to decision

K211546 · Product code: **DQK** · Cardiovascular
Source: https://www.510kdatabase.net/k211546/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	May 19, 2021
Decision date	Nov 9, 2021
Days to decision	174 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Vektor Medical, Inc.**
Location	Carlsbad, CA, US
Contact	Mike Monko
510(k) history	2 submissions · 2 cleared · 2021-2025

REGULATORY CONSULTANT

Consulting firm	**Experien Group, LLC**
Contact	Michael J Billig

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

CLINICAL EVIDENCE - NCT04559061

Vektor vMap™ Clinical Validation Study

Status	Completed - *No results published to ClinicalTrials.gov*
Enrollment	225 patients (actual)
Study sites	4 sites
Condition studied	Cardiac Arrhythmia; Atrial Fibrillation; Ventricular Arrythmia; Premature Ventricular Complexes Multiple; Ventricular Tachycardia; Ventricular Fibrillation; Premature Atrial Complex; Atrioventricular Reentrant Tachycardia
Study type	Observational
Completion date	Apr 6, 2021
Sponsor	Vektor Medical (Industry)

Primary outcome

Rate of accuracy/agreement of vMap™ in correctly identifying the ventricular chamber/region of the arrhythmia for PCV and VT.

Secondary outcome

Rate of accuracy/agreement of vMap™ in correctly identifying the chamber/region of the arrhythmia location for all arrhythmia types.

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT04559061