FDA 510(k) Premarket Notification

K183195 VIVO

CLEARED

Jun 14, 2019
207 days to decision

K183195 · Product code: **DQK** · Cardiovascular
Source: https://www.510kdatabase.net/k183195/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Nov 19, 2018
Decision date	Jun 14, 2019
Days to decision	207 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Catheter Precision, Inc.**
Location	Ledgewood, NJ, US
Contact	Steve Adler
510(k) history	2 submissions · 2 cleared · 2019-2020

CLINICAL EVIDENCE - NCT03340142

VIVO™ Accuracy Study

Status	Completed - *No results published to ClinicalTrials.gov*
Enrollment	45 patients (actual)
Study sites	3 sites
Condition studied	Premature Ventricular Contraction; Ventricular Tachycardia
Primary purpose	Diagnostic
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Nov 1, 2018
Sponsor	Catheter Precision. Inc. (Industry)

Primary outcome

Accuracy of correctly identifying PVC or VT origin

Secondary outcome

Accuracy of correctly identifying known pacing sites

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT03340142