FDA 510(k) Premarket Notification

K200313 VIVO

CLEARED

Sep 14, 2020
221 days to decision

K200313 · Product code: **DQK** · Cardiovascular
Source: https://www.510kdatabase.net/k200313/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Feb 6, 2020
Decision date	Sep 14, 2020
Days to decision	221 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