FDA 510(k) Premarket Notification

K212593 ViaCath, AcQRate Dx Steerable Catheter

CLEARED

Oct 15, 2021
60 days to decision

K212593 · Product code: **DRF** · Cardiovascular
Source: https://www.510kdatabase.net/k212593/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Electrode Recording, Or Probe, Electrode Recording (DRF)
Date received	Aug 16, 2021
Decision date	Oct 15, 2021
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Biotronick, Inc.**
Location	Lake Oswego, OR, US
Contact	Jon Brumbaugh
510(k) history	1 submissions · 1 cleared · 2021-2021