

K212593 ViaCath, AcQRate Dx Steerable CatheterOct 15, 2021
60 days to decisionK212593 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212593/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026