

K203793 RithmID-SD Steerable Diagnostic Electrophysiology CatheterFeb 14, 2022
413 days to decisionK203793 · Product code: **DRF** · Cardiovascular
Source: <https://www.510kdatabase.net/k203793/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Electrode Recording, Or Probe, Electrode Recording (DRF)
Date received	Dec 28, 2020
Decision date	Feb 14, 2022
Days to decision	413 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Synaptic Medical Corporation
Location	Carlsbad, CA, US
Contact	Charles Yang
510(k) history	4 submissions · 4 cleared · 2022-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k203793/> 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 25, 2026