FDA 510(k) Premarket Notification

CLEARED

K203793 RithmID-SD Steerable Diagnostic Electrophysiology Catheter

Feb 14, 2022
413 days to decision

K203793 · 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