FDA 510(k) Premarket Notification

CLEARED

K233900 Nordica PV Cryo Mapping Catheter

Sep 6, 2024
270 days to decision

K233900 · Product code: **DRF** · Cardiovascular
Source: https://www.510kdatabase.net/k233900/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Electrode Recording, Or Probe, Electrode Recording (DRF)
Date received	Dec 11, 2023
Decision date	Sep 6, 2024
Days to decision	270 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k233900/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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