

K133028 RITHM ID ELECTROPHYSIOLOGY CATHETERMar 4, 2014
159 days to decisionK133028 · Product code: **DRF** · Cardiovascular
Source: <https://www.510kdatabase.net/k133028/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Electrode Recording, Or Probe, Electrode Recording (DRF)
Date received	Sep 26, 2013
Decision date	Mar 4, 2014
Days to decision	159 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Synaptic Medical Limited
Location	Shanghai, CN
Contact	Diana Hong
510(k) history	3 submissions · 2 cleared · 2014-2015

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k133028/> 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 June 3, 2026