

K182386 Reprocessed Supreme Diagnostic Electrophysiology CatheterApr 23, 2019
231 days to decisionK182386 · Product code: **DRF** · Cardiovascular
Source: <https://www.510kdatabase.net/k182386/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Electrode Recording, Or Probe, Electrode Recording (DRF)
Date received	Sep 4, 2018
Decision date	Apr 23, 2019
Days to decision	231 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Innovative Health, LLC
Location	Scottsdale, AZ, US
Contact	Amanda Babcock
510(k) history	48 submissions · 48 cleared · 2016-2024

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