

**K191880 Reprocessed Achieve Advance Mapping Diagnostic  
Electrophysiology Catheter**Dec 11, 2019  
149 days to decisionK191880 · Product code: **DRF** · Cardiovascular  
Source: <https://www.510kdatabase.net/k191880/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Electrode Recording, Or Probe, Electrode Recording (DRF)
Date received	Jul 15, 2019
Decision date	Dec 11, 2019
Days to decision	149 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k191880/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 28, 2026