

**K191170 Reprocessed Reflexion Spiral Bi-Directional Variable Radius Electrophysiology Catheter**Oct 30, 2019  
182 days to decisionK191170 · Product code: **NLH** · Cardiovascular  
Source: <https://www.510kdatabase.net/k191170/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Recording, Electrode, Reprocessed (NLH)
Date received	May 1, 2019
Decision date	Oct 30, 2019
Days to decision	182 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/k191170/> 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