

K182488 Reprocessed Response Diagnostic Electrophysiology CatheterFeb 22, 2019
164 days to decisionK182488 · Product code: **NLH** · Cardiovascular
Source: <https://www.510kdatabase.net/k182488/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Recording, Electrode, Reprocessed (NLH)
Date received	Sep 11, 2018
Decision date	Feb 22, 2019
Days to decision	164 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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