

K181897 Reprocessed Mariner Diagnostic EP CatheterNov 15, 2018
122 days to decisionK181897 · Product code: **NLH** · Cardiovascular
Source: <https://www.510kdatabase.net/k181897/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Recording, Electrode, Reprocessed (NLH)
Date received	Jul 16, 2018
Decision date	Nov 15, 2018
Days to decision	122 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k181897/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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