

K181458 Reprocessed Advisor FL Sensor Enabled Circular Mapping Catheter

Oct 27, 2018
145 days to decision

K181458 · Product code: **NLH** · Cardiovascular
Source: <https://www.510kdatabase.net/k181458/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Recording, Electrode, Reprocessed (NLH)
Date received	Jun 4, 2018
Decision date	Oct 27, 2018
Days to decision	145 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.net

Device record: <https://www.510kdatabase.net/k181458/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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