

K180710 Reprocessed DecaNav Diagnostic Electrophysiology Catheter

Jun 19, 2018
92 days to decision

K180710 · Product code: **NLH** · Cardiovascular
Source: <https://www.510kdatabase.net/k180710/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Recording, Electrode, Reprocessed (NLH)
Date received	Mar 19, 2018
Decision date	Jun 19, 2018
Days to decision	92 days
Third-party review	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/k180710/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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