

K153153 Reprocessed Electrophysiology CatheterMar 14, 2016
133 days to decisionK153153 · Product code: **NLH** · Cardiovascular
Source: <https://www.510kdatabase.net/k153153/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Recording, Electrode, Reprocessed (NLH)
Date received	Nov 2, 2015
Decision date	Mar 14, 2016
Days to decision	133 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Innovative Health, LLC
Location	Scottsdale, AZ, US
Contact	RAFAL CHUDZIK
510(k) history	48 submissions · 48 cleared · 2016-2024

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