

K161464 Reprocessed Dynamic Tip Steerable Diagnostic Electrophysiology Catheters

Sep 30, 2016
127 days to decisionK161464 · Product code: **NLH** · Cardiovascular
Source: <https://www.510kdatabase.net/k161464/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Recording, Electrode, Reprocessed (NLH)
Date received	May 26, 2016
Decision date	Sep 30, 2016
Days to decision	127 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k161464/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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