

K211276 Reprocessed Dynamic Tip and XT Steerable Diagnostic Electrophysiology Catheters

Sep 15, 2021
141 days to decisionK211276 · Product code: **NLH** · Cardiovascular
Source: <https://www.510kdatabase.net/k211276/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Recording, Electrode, Reprocessed (NLH)
Date received	Apr 27, 2021
Decision date	Sep 15, 2021
Days to decision	141 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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Device record: <https://www.510kdatabase.net/k211276/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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