

K160496 Reprocessed Inquiry Steerable Diagnostic EP CatheterJun 10, 2016
109 days to decisionK160496 · Product code: **NLH** · Cardiovascular
Source: <https://www.510kdatabase.net/k160496/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Recording, Electrode, Reprocessed (NLH)
Date received	Feb 22, 2016
Decision date	Jun 10, 2016
Days to decision	109 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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