

**K160421 Reprocessed Inquiry Optima Plus Steerable
Diagnostic EP Catheter, Reprocessed Inquiry Optima Steerable
Diagnostic EP Catheter**Nov 2, 2016
260 days to decisionK160421 · Product code: **NLH** · Cardiovascular
Source: <https://www.510kdatabase.net/k160421/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Recording, Electrode, Reprocessed (NLH)
Date received	Feb 16, 2016
Decision date	Nov 2, 2016
Days to decision	260 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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