

**K161393 Reprocessed Orbiter ST Steerable Diagnostic EP Catheter**Oct 26, 2016  
160 days to decisionK161393 · Product code: **NLH** · Cardiovascular  
Source: <https://www.510kdatabase.net/k161393/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Recording, Electrode, Reprocessed (NLH)
Date received	May 19, 2016
Decision date	Oct 26, 2016
Days to decision	160 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Innovative Health, LLC</b>
Location	Scottsdale, AZ, US
Contact	Rafal Chudzik
510(k) history	48 submissions · 48 cleared · 2016-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k161393/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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