

**K170922 Reprocessed Webster CS Bi-Directional Diagnostic EP Catheter, Reprocessed Webster CS Bi-Directional Diagnostic EP Catheter (with Auto ID)**

Jun 22, 2017  
85 days to decision

K170922 · Product code: **NLH** · Cardiovascular  
Source: <https://www.510kdatabase.net/k170922/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Recording, Electrode, Reprocessed (NLH)
Date received	Mar 29, 2017
Decision date	Jun 22, 2017
Days to decision	85 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Innovative Health, LLC</b>
Location	Scottsdale, AZ, US
Contact	Amy Stoklas-Oakes
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/k170922/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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