

K171788 Reprocessed Halo XP Diagnostic Electrophysiology CatheterNov 3, 2017
141 days to decisionK171788 · Product code: **NLH** · Cardiovascular
Source: <https://www.510kdatabase.net/k171788/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Recording, Electrode, Reprocessed (NLH)
Date received	Jun 15, 2017
Decision date	Nov 3, 2017
Days to decision	141 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k171788/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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