

K171277 Reprocessed Inquiry Steerable Diagnostic EP CatheterOct 23, 2017
175 days to decisionK171277 · Product code: **DRF** · Cardiovascular
Source: <https://www.510kdatabase.net/k171277/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Electrode Recording, Or Probe, Electrode Recording (DRF)
Date received	May 1, 2017
Decision date	Oct 23, 2017
Days to decision	175 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/k171277/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 31, 2026