

**K221067 Medline ReNewal Reprocessed St. Jude Medical
Livewire Steerable Electrophysiology Catheter**May 31, 2023
414 days to decisionK221067 · Product code: **NLH** · Cardiovascular
Source: <https://www.510kdatabase.net/k221067/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Recording, Electrode, Reprocessed (NLH)
Date received	Apr 12, 2022
Decision date	May 31, 2023
Days to decision	414 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Surgical Instrument Service and Savings, Inc.
Location	Redmond, OR, US
Contact	Stephanie Boyle Mays
510(k) history	23 submissions · 23 cleared · 2016-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k221067/> 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 13, 2026