

K241156 Medline ReNewal Reprocessed St. Jude Medical Response Electrophysiology Catheter, Supreme Electrophysiology Catheter (401150, 401206, 401207, 401210, 401211, 401212, 401222, 401223, 401226, 401227, 401228, 401260, 401261, 401271, 401305, 401306, 401309, 401310, 401311, 401312, 401317, 401353, 401357, 401381, 401392, 401399, 401400, 401425, 401430, 401433, 401434, 401435, 401436, 401438, 401441, 401442, 401443, 401444, 401445, 401448, 401449, 401450, 401451, 401453, 401466, 401468, 401

Sep 14, 2024
141 days to decision

K241156 · Product code: NLH · Cardiovascular
Source: <https://www.510kdatabase.net/k241156/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Recording, Electrode, Reprocessed (NLH)
Date received	Apr 26, 2024
Decision date	Sep 14, 2024
Days to decision	141 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
