

K121158 REPROCESSED ELECTROPHYSIOLOGY DIAGNOSTIC CATHETERSAug 6, 2012
112 days to decisionK121158 · Product code: **NLH** · Cardiovascular
Source: <https://www.510kdatabase.net/k121158/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Recording, Electrode, Reprocessed (NLH)
Date received	Apr 16, 2012
Decision date	Aug 6, 2012
Days to decision	112 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sterilmed, Inc.
Location	Plymouth, MN, US
Contact	JASON SKRAMSTED
510(k) history	64 submissions · 64 cleared · 2001-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k121158/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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