K121158 REPROCESSED ELECTROPHYSIOLOGY DIAGNOSTIC CATHETERS

CLEARED

Aug 6, 2012
112 days to decision

K121158 · 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