FDA 510(k) Premarket Notification

K101789 REPROCESSED ELECTROPHYSIOLOGY DIAGNOSTIC CATHETERS

CLEARED

Aug 19, 2010
52 days to decision

K101789 · Product code: **NLH** · Cardiovascular
Source: https://www.510kdatabase.net/k101789/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Recording, Electrode, Reprocessed (NLH)
Date received	Jun 28, 2010
Decision date	Aug 19, 2010
Days to decision	52 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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