FDA 510(k) Premarket Notification

K150357 Reprocessed Electrophysiology Diagnostic Catheters

CLEARED

Aug 27, 2015
196 days to decision

K150357 · Product code: **NLH** · Cardiovascular
Source: https://www.510kdatabase.net/k150357/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Recording, Electrode, Reprocessed (NLH)
Date received	Feb 12, 2015
Decision date	Aug 27, 2015
Days to decision	196 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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