FDA 510(k) Premarket Notification

K100254 REPROCESSED CS BI-DIECTIONAL DIAGNOSTIC ELECTROPHYSIOLOGY CATHETER

CLEARED

May 28, 2010
120 days to decision

K100254 · Product code: **NLH** · Cardiovascular
Source: https://www.510kdatabase.net/k100254/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Recording, Electrode, Reprocessed (NLH)
Date received	Jan 28, 2010
Decision date	May 28, 2010
Days to decision	120 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Ascent Healthcare Solutions**
Location	Phoenix, AZ, US
Contact	AMANDA BABCOCK
510(k) history	21 submissions · 21 cleared · 2006-2011