FDA 510(k) Premarket Notification

K122461 RHYTHMIA MAPPING CATHETER

CLEARED

Apr 18, 2013
248 days to decision

K122461 · Product code: **DRF** · Cardiovascular
Source: https://www.510kdatabase.net/k122461/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Electrode Recording, Or Probe, Electrode Recording (DRF)
Date received	Aug 13, 2012
Decision date	Apr 18, 2013
Days to decision	248 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Rhythmia Medical, Inc.**
Location	Burlington, MA, US
Contact	LEON AMARIGLIO
510(k) history	3 submissions · 3 cleared · 2013-2015