FDA 510(k) Premarket Notification

K092003 CPC SLEEP DATA RECORDER, MODEL M1, AND APPLICATION SOFTWARE

CLEARED

Sep 30, 2009
90 days to decision

K092003 · Product code: **MNR** · Anesthesiology
Source: https://www.510kdatabase.net/k092003/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilatory Effort Recorder (MNR)
Date received	Jul 2, 2009
Decision date	Sep 30, 2009
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**MyCardio, LLC**
Location	Broomfield, CO, US
Contact	ROBERT SCHUEPPERT
510(k) history	1 submissions · 1 cleared · 2009-2009