

K163696 SleepImage SystemOct 13, 2017
288 days to decisionK163696 · Product code: **MNR** · Anesthesiology
Source: <https://www.510kdatabase.net/k163696/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilatory Effort Recorder (MNR)
Date received	Dec 29, 2016
Decision date	Oct 13, 2017
Days to decision	288 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Mycardio, LLC Db a Sleepimage.
Location	Broomfield, CO, US
Contact	Robert Schueppert
510(k) history	2 submissions · 2 cleared · 2017-2019

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