

K182618 SleepImage SystemAug 14, 2019
324 days to decisionK182618 · Product code: **MNR** · AnesthesiologySource: <https://www.510kdatabase.net/k182618/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilatory Effort Recorder (MNR)
Date received	Sep 24, 2018
Decision date	Aug 14, 2019
Days to decision	324 days
Third-party review	No
Combination product	No
PCCP authorized	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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