

K191031 NightOwlMar 6, 2020
323 days to decisionK191031 · Product code: **MNR** · Anesthesiology
Source: <https://www.510kdatabase.net/k191031/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilatory Effort Recorder (MNR)
Date received	Apr 18, 2019
Decision date	Mar 6, 2020
Days to decision	323 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ectosense NV
Location	Rotselaar, BE
Contact	Bart Van Pee
510(k) history	3 submissions · 3 cleared · 2020-2022

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