

K213463 NightOwlDec 16, 2021
50 days to decisionK213463 · Product code: **MNR** · AnesthesiologySource: <https://www.510kdatabase.net/k213463/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Ventilatory Effort Recorder (MNR)
Date received	Oct 27, 2021
Decision date	Dec 16, 2021
Days to decision	50 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213463/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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