

K231355 AuroraFeb 9, 2024
275 days to decisionK231355 · Product code: **MNR** · AnesthesiologySource: <https://www.510kdatabase.net/k231355/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Ventilatory Effort Recorder (MNR) |
| Date received | May 10, 2023 |
| Decision date | Feb 9, 2024 |
| Days to decision | 275 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Ensodata |
| Location | Madison, WI, US |
| Contact | Sigrid Schoepel |
| 510(k) history | 1 submissions · 1 cleared · 2024-2024 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k231355/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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