

K243220 Onera STS 2 (ONERA STS 2)Jul 3, 2025
269 days to decisionK243220 · Product code: **MNR** · Neurology
Source: <https://www.510kdatabase.net/k243220/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilatory Effort Recorder (MNR)
Date received	Oct 7, 2024
Decision date	Jul 3, 2025
Days to decision	269 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Onera B.V.
Location	Eindhoven, NL
Contact	Pieter Ermers
510(k) history	4 submissions · 4 cleared · 2022-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243220/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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